DEVELOPING A FRAMEWORK FOR

CARBOHYDRATE AWARENESS ADVICE IN TYPE TWO DIABETES

by

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Dedication

This thesis is dedicated to Phil. Thank you for all your love and encouragement.

Abstract

Type 2 Diabetes (T2DM) is a long-term condition in which dietary management is central, however there remains uncertainty about the most effective way to advise patients with T2DM about carbohydrate, even amongst Registered Dietitians (RDs). This research aimed to develop a framework for carbohydrate awareness advice using mixed methods research.

Firstly, a meta-analysis found that evidence is lacking for a widespread carbohydrate restriction but restricting to below 130g per day offers short-term benefits for improving glycaemic control. The qualitative study involving interviews with people with T2DM and focus groups with RDs highlighted the importance of individualising advice for patients and identified helpful and unhelpful aspects of RD advice. RD reported practice varies, however they were able to describe carbohydrate awareness advice and outline key areas for professional development. Kleinman's Explanatory Model and related concepts were applied to the findings from the two qualitative parts of the research and the systematic review. This allowed the construction of the Carbohydrate Awareness Advice Framework (CAAF) using the findings from this research and based on a strong theoretical foundation.

The CAAF incorporates the findings from both the quantitative and qualitative research conducted for this thesis and should form the basis for an intervention in future clinical trials.

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Contributorship Statement

All of the Chapters within this thesis are entirely the product of my own work, with the support and guidance of my supervisors Professor Sheila Greenfield and Professor Paramjit Gill.

The systematic review and meta-analysis presented as a paper in **Chapter Two** was published prior to examination of this thesis. The study was conceived and designed by PDM, PSG and SMG. In addition, Dr Trudi Deakin & Dr Sarah Damery both commented on the initial protocol. PDM and SKR undertook the literature search and data extraction. MSH contributed to the statistical analysis. PDM wrote the first draft of the manuscript, and all authors contributed to the critique and editing of the manuscript.

Thesis Format

This thesis is presented in accordance with The University of Birmingham Alternative Thesis Format Guidelines, which allows for the inclusion of Chapters which are in the format of a paper suitable for publication in a peer-reviewed journal.

Chapter Two has been published and is presented in the format in which it is published in the journal. As such, the page numbers do not follow the pagination sequence of the submission and it has self-contained references, tables and figures.

An extract from the University of Birmingham Alternative Format Thesis Guidelines (section 10(:

> *"The incorporation of publication-style chapters in the thesis will inevitably lead to some duplication since each publication-style chapter will have self-contained components that will overlap with parts of other sections of the thesis."*

The University guidelines can be read in full:

https://intranet.birmingham.ac.uk/as/studentservices/graduateschool/documents/public/rsa/alternative-format-thesis-guidelines.pdf

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LIST OF ABBREVIATIONS

A	ADA	American Diabetes Association
C	CCGs	Clinical Commissioning Groups
D	DPP	Diabetes Prevention Programme
E	EBM	Evidence-Based Medicine
	EM	Explanatory Model
F	FGs	Focus Groups
G	GP	General Practitioner
H	HbA1c	Glycated Haemoglobin
N	NHS	National Health Service
P	PWD	People / Person with Diabetes
R	RD	Registered Dietitian
	REC	Research Ethics Committee
T	T1DM	Type 1 Diabetes Mellitus
	T2DM	Type 2 Diabetes Mellitus
W	WHO	World Health Organisation

CHAPTER ONE

INTRODUCTION & BACKGROUND

This thesis addresses the complex area of carbohydrate advice in type 2 diabetes (T2DM). This Chapter describes why the topic is important, the historical perspective and context of this study, the links between previous research and this study and then presents the research questions and objectives before describing the structure of the thesis. This thesis has a UK focus, however the evidence base is globally-derived and therefore reference is made, where relevant, to international data and guidelines (in particular the USA and Europe) for completeness and occasionally comparison purposes.

This thesis and the work on which it is based represents the culmination of a personal and professional journey which began in 2009, about 8 years into my career as a Registered Dietitian (RD).

Within 3 years of qualifying as an RD an opportunity arose to work as part of a specialist diabetes multidisciplinary team (MDT) which, although not part of my original career planning, was an attractive prospect to develop within a specialist field. I was already active within the voluntary roles of our professional association, The British Dietetic Association (BDA), which gave access and insight to developments within the field, ultimately joining the Committee of the Diabetes Specialist Group of the BDA. By 2009 it was clear that the UK Nutrition Guidelines for Diabetes were overdue for an update, having last been published in 2003.[1] My journey into evidence-based practice and research began as a result of being part of the update of this document, owned by the charity Diabetes UK.

The update of the guidelines was a group effort with a large number of experts and interested parties recruited to do so and the entire process was overseen by Diabetes UK. It took about 2 years and they were published in 2011.[2] Throughout this work I was frequently surprised by the lack of robust research on which to base the recommendations, even to the extent that some recommendations from the previous iteration of the document had to be removed and were not replaced with anything equivalent, meaning there were significant gaps in our understanding. In particular, the recommendations around carbohydrate and, more specifically, the recommendation about how much carbohydrate had to be removed. This was previously expressed in clear terms as a proportion or percentage of total energy. As a professional I found the removal of this quite definite recommendation liberating and could see the opportunity for applying this to individuals rather than pigeon-holing patients to a fixed recommended amount. However, I recall being confronted at a conference by two RDs who were appalled at the removal of this concrete recommendation from the guidelines, despite the lack of evidence to support it, asking "what do we tell our patients now…?". I had already been reflecting on how RDs might interpret this new approach to carbohydrate recommendations and, when the opportunity arose to undertake a Masters in Research Methods in 2012, it was clear that understanding dietitians' practice in this area was worthy of research given the recent guideline changes. This therefore led directly to my research which was later published in 2016 'Dietitians Practice in Giving Carbohydrate Advice in Type 2 Diabetes: A Mixed Methods Study.'.[3]

One term or phrase stood out as lacking clarity yet being ubiquitous in the advice given by dietitians for patients with T2DM: 'Carbohydrate Awareness Advice' ('CAA'). This form of

advice which had become part of the vernacular amongst diabetes professionals was in dire need of definition and study, and it was my intention to do this. The research I planned to do when preparing an application for the National Institute for Health Research (NIHR) Clinical Doctoral Fellowship (CDRF) involved a qualitative study to define the meaning and use of the term, followed by a feasibility study to model the process in preparation for a full-scale trial. It became clear in the final stages prior to submitting the application for the CDRF that the plan was over-ambitious and, according to advice received, the funding body expects to see a systematic review with or without meta-analysis prior to the development of any new intervention such as this. Therefore, the feasibility study was removed from the application and a systematic review with meta-analysis added to the start of the research plan in its place. Throughout this process the sense of encouragement and desire for something of practical use by the profession has been palpable and at every opportunity RDs would ask me about the progress towards developing CAA. This has felt like a big responsibility and simultaneously a great opportunity to help to develop the profession and has been the driving force behind this work for many years, satisfying both my desire to develop research skills and the dual role of a passionate clinician working in diabetes.

1.1 Background

Defining Diabetes & Types of Diabetes

Diabetes is a condition in which the level of glucose in the blood becomes too high, either due to a lack of production of the hormone insulin or because of poor sensitivity to the effects of insulin (known as 'insulin resistance').[4] Insulin allows glucose to move from the blood into body cells where it can be used in energy production. Both insulin insufficiency and insulin resistance will result in the build-up of glucose in the blood, which in turn can lead to

significant physiological damage, in particular to the circulatory (small and large blood vessels) and nervous systems.[4]

There are several different types of diabetes and the most common forms are Type 1 diabetes (T1DM) and T2DM. In T1DM, the insulin-producing beta-cells in the pancreas are destroyed as part of an autoimmune response to a yet unknown trigger. The result is a lifetime requirement for insulin replacement therapy. T1DM will not be discussed further in this thesis. Despite the similar name, T2DM is a different condition, characterised by insulin resistance rather than absolute insulin insufficiency. T2DM is closely linked to obesity and lifestyle, making it highly preventable among at risk groups.[5]

Diagnosing Diabetes

Diagnosis of T2DM is typically either opportunistic through routine health monitoring or via targeted screening in at risk populations.[6] Non-modifiable risk factors for the development of T2DM include age, family history, gender and ethnicity.[7] The onset of T2DM can be very gradual and many people will have no symptoms at the point of diagnosis [8], however the most common symptoms experienced are thirst (polydipsia), excessive tiredness and an increased need to pass urine (polyuria). The diagnosis is confirmed by either venous blood glucose or glycated haemoglobin (HbA1c) and the current World Health Organisation [9] criteria for the diagnosis of diabetes are summarised below:

- Fasting plasma glucose $\geq$ 7.0 mmol/l or
- 2-h plasma glucose $\geq$ 11.1 mmol/l two hours after 75g anhydrous glucose as part of an oral glucose tolerance test or as a random plasma glucose.
- HbA1c of $\geq$ 6.5% (48 mmol/mol)

It is also recommended to repeat the test before making a diagnosis if there are no symptoms present. The addition of HbA1c for diagnosing diabetes was part of an addendum to the 2006 diagnostic criteria, published in 2011.[8]

As the diagnosis of T2DM is based on a numerical cut-off, and it can be made without the need for any obvious symptoms, this may contribute to feelings of denial that have been reported in research examining patients feelings about the diagnosis.[10] There is a lack of research specifically relating to the experiences of people diagnosed with T2DM, however drawing on the published literature from other chronic conditions, patients may also experience feelings of insecurity, shame and guilt.[11]

UK & Global Health Burden

Diabetes affects 4.5 million people in the UK with a reported prevalence of 6.8% in England in 2018.[12] Approximately 90% of people living with diabetes in the UK have T2DM.[13] Diabetes is estimated to affect 451 million globally, with numbers rising annually, predominantly in T2DM, in both industrialised and developing countries.[14] The global increase in diabetes is linked to increasing worldwide obesity, which has increased by 27.5% for adults between 1980 and 2013.[15]

Diabetes is a complex, chronic condition that can lead to a wide range of complications and accounts for 10% of the NHS budget, or about £1 million per hour, with almost 80% of this spent treating the complications of diabetes.[16] This figure is expected to rise to 17% of the NHS budget by 2035 due to the increasing numbers of people living with diabetes and resulting health costs from treating diabetes and its complications.[16] As well as the rising

number of prescriptions for diabetes treatments, another factor affecting the cost to the health service may be the increased availability of newer technologies and the continual development of new treatments by the pharmaceutical industry.[17] The personal costs of diabetes are also significant, with life expectancy reduced by 6 years [18] and diabetes cited as one of the leading causes of kidney disease and blindness in working-age adults.[19] The most recent Global Burden of Disease data suggests that, whilst death rates and years of lost life due to communicable diseases have decreased, for diabetes they have increased and the condition has gone from the 28th leading cause in 1990 to number 15 in 2017.[20] This is likely due to the significant increase in the prevalence of T2DM and its links with unhealthy lifestyles.

However, diabetes can be prevented and data from diabetes prevention trials show consistently that modest weight loss of 5-7%, alongside other lifestyle changes, can lead to a 50% reduction in progression to T2DM [21] with some suggesting up to 80% reduction following 10% weight loss.[22] The UK was the first country to implement a national NHS Diabetes Prevention Programme (DPP) in 2017, aimed at implementing an evidence-based approach to preventing diabetes and to reduce future growth in the number of people with T2DM.[23] Self-management behaviours, particularly lifestyle changes to modify diet & exercise, and which result in weight loss in the overweight, remain an important focus once an individual is diagnosed with T2DM. Recent research suggests that diabetes remission as a result of weight loss is a realistic possibility for up to half of people living with the condition, particularly in the first 6 years of T2DM.[24]

Diabetes Self-Management

In the UK, the person living with diabetes is expected to take the main responsibility for managing their own condition, in conjunction with support from health professionals. Living with diabetes involves making daily decisions about food choices, taking medications correctly, self-monitoring of blood glucose and visiting a health professional such as their GP or Practice Nurse for support and surveillance regarding complications.[25] Diabetes UK [26] estimates that people with diabetes spend just three hours per year with a health professional, highlighting the significant responsibility of self-management for people living with the condition. Indeed, self-management is not an activity that patients with chronic conditions undertake on their own, as noted by Dwarswaard,[27] who outlined the main types of support patients require as instrumental, psychosocial and relational support. The objectives of this thesis are concerned principally with the instrumental form of support, that is; giving information and improving patients' knowledge about self-management of their condition. However, the psychosocial and relational support should not be overlooked. A study which examined patient attitudes towards diabetes and reasons for disengagement in care also found cognitive, behavioural and emotional factors as relevant,[28] describing food as 'strongly emotional' at a symbolic level. Recognising this is important for health professionals wishing to affect changes in eating habits. In fact, it is recognised that merely the content of health professionals' conversations with patients in chronic disease may not be sufficient to lead to behaviour change.[29] This emphasises the importance of developing a positive therapeutic relationship and acknowledging diabetes as a source of distress and impacting on quality of life.[30]

People with diabetes seek out and obtain health information from a number of sources, including health care professionals and the internet,[31] friends, family and other media.[32] This may be linked to how they view their illness, its origins and how to manage it, and forms part of what Kleinman [33] describes as the patient's 'Explanatory Model' (EM). Understanding and exploring the patient's EM can have a significant impact on how patients approach self-management, how they interact with health professionals, and subsequently the quality of care. Although lay EMs are said to be characterised by 'vagueness and impreciseness',[34] there is value in understanding and incorporating the theory of EMs as part of research which will inform the development of a health care intervention. The theory of EMs is based on the social and cultural nature of illness, recognising that beyond simply the acquisition of knowledge or information, patients must then make sense of that information within their own EM in order to make decisions about application. According to Kleinman,[35] health care takes place in multiple domains or arenas, including the "popular", "folk" & "professional", with the majority of health care occurring in the popular domain (friends, family, media). He also highlights the importance of viewing illness (or in this case, self-management of illness) in a social and cultural context. These concepts are particularly relevant to this thesis given the highly cultural and social nature of food and eating.[36] Food, eating and decisions about what to eat are recognised to be heavily influenced by cultural norms, traditions, social circumstances and preference [37] and are part of a complex identity.[38] It must therefore be argued that health professionals giving dietary advice ought to have some understanding of this context if their advice is to be acceptable and useful to their patients.

Alongside self-management, effective diabetes management also requires a multi-disciplinary approach with biomedical input including health professionals with specific

competencies in nutrition,[39] such as RDs, working in collaboration with the person with diabetes to achieve a successful therapeutic relationship. Registered Dietitians are the professional group on which this thesis is focussed.

1.2 UK Policy Context

The NHS Five Year Forward View [40] placed a strong emphasis on the importance of empowering patients and reducing variations in the quality of care. This is in the context of rising rates of obesity and T2DM and highlights the three key aspects of quality: patient safety, clinical effectiveness and patient experience. More recently, the NHS Long Term Plan,[41] focusses on reducing health inequalities and variation in diabetes care between CCGs, including a doubling of the provision of the NHS DPP and the introduction of digital technologies in both the prevention and management of diabetes. The plan does not specifically address the issue of dietary advice, however there is a commitment to improving the nutrition training provided in medical schools.

This thesis addresses important questions regarding clinical effectiveness and patient experience in the area of carbohydrate advice and T2DM, since there is currently a dearth of research regarding patient experience in this area and the current evidence around carbohydrate is somewhat confusing. This thesis is well-aligned with the current policy context in the UK as it has the potential to inform the development of interventions that may contribute to the reductions in inequality and variations in care that are a key priority in the NHS Long Term Plan,[41] by improving carbohydrate advice provided by dietitians and other health professionals and thereby supporting patients' self-management.

1.3 The Dietetic Profession

Registered Dietitians are one of 16 Professions regulated by the Health & Care Professions Council [42] signified by the suffix 'RD'. Dietetics is a relatively new profession; the first dietitians were in fact nurses [43] and the profession became more formally recognised in the UK with specific training provided by colleges in the early twentieth century.[44] The role of the dietitian has changed over this time period and RDs are now autonomous Health Professionals, meaning they are educated to degree level, practice under an ethical code according to the standards set by the HCPC and are the only health professionals in the UK specifically qualified to diagnose and treat nutritional problems. RDs work in a variety of areas besides healthcare, including the food industry, research and academia, sports, education and government.[45] The key skill of clinical RDs is in translating the science of nutrition into practical information and advice that meets the therapeutic goals of individuals. There are many physical health conditions in which this is a vital tool in prevention or management of the condition, but T2DM is a particularly good example due to its strong links with lifestyle. The most recent development in the role of the RD was a change in the law in February 2016 which introduced prescribing rights,[46] meaning RDs can now become Supplementary Prescribers. This further enhances the opportunities for dietitians to provide a holistic approach to the care of people with T2DM .

1.4 Nutrition & the role of carbohydrate in T2DM

Nutrition interventions (sometimes referred to as 'Medical Nutrition Therapy' or 'MNT") in diabetes have demonstrated clinically significant improvements in blood glucose control, as measured by the glycated haemoglobin or 'HbA1c',[47] which is typically taken as a venous sample and reflects the level of glucose in the blood over the preceding 8-12 weeks. This

measure is routinely used as a marker of blood glucose control and more recently as a diagnostic test for diabetes.[25,48] A reduction of 11 mmol/mol in HbA1c is considered a clinically significant change and is associated with a reduced rate of complications, as shown in the United Kingdom Prospective Diabetes Trial (UKPDS).[49] A range of dietary approaches appear to be effective in the management of T2DM including several popular diets [50,51] and nutrition interventions have shown up to 23mmol/mol reduction in HbA1c,[47] suggesting their successful implementation can significantly reduce the risk of complications. The principal focus is on weight management in those who are overweight, however there is significant controversy and a lack of evidence regarding the optimal macronutrient (i.e. fat, protein and carbohydrate) proportions required for people with T2DM.[52] This controversy and lack of evidence is central to the need to undertake the research contained within this thesis.

Carbohydrate is the macronutrient that has the greatest impact on postprandial (after meal) blood glucose increases and is therefore the nutrient of principal interest in the diets of people with diabetes. However, as there is insufficient evidence to recommend a specific quantity of carbohydrate, the debate continues in this area with the most recent national nutrition guidelines advising an 'individualised' approach.[53] This uncertainty has led to the possibility for variations in clinical practice that are not clearly justified or understood. There is a lack of research into the practice of Registered Dietitians (RDs), however one such study which informed this thesis found there was variation in how RDs advise people with T2DM about carbohydrate.[3] In particular, there was variation in the meaning and use of 'Carbohydrate Awareness Advice', a form of advice that dietitians reported using frequently with their patients yet are unable to concisely and consistently define. A recent qualitative study of UK RDs found that practice does not fully reflect the current evidence base and that

dietitians have a wide range of concerns regarding the potential disadvantages of low carbohydrate dietary approaches.[54]

Research suggests that greater public exposure to contradictory nutrition information leads to increased confusion and a reduced intent to change lifestyle.[55] This clearly emphasises the importance of clear communication of nutrition information and suggests it may also be important for health professionals to be consistent in their advice, although there is limited research into the effects of conflicting health information.[56] It is therefore worthwhile to review the recent history with regards to carbohydrate advice in T2DM and how this has changed over time and how it differs according to national guidelines. As this thesis concerns T2DM, this brief history of carbohydrate advice will begin from the point at which the two main types of diabetes were first differentiated.

1.5 A brief history of carbohydrate advice as part of dietary advice for T2DM (1936 – 2018)

T1DM and T2DM were first differentiated in 1936,[57] albeit not under those terms. It is therefore prudent to study the changes in dietary advice and guidelines since that time, of which there have been several. Early diets for diabetes focussed on severe carbohydrate restriction, followed by a 30-year period of relative dietary freedom up until the 1960s, which caused great controversy.[58]

The ADA recommended the use of carbohydrate 'exchanges' in the 1960s as a means of controlling blood glucose by counting 15g carbohydrate exchanges and prescribing individuals a fixed number of exchanges per day, distributed across meals and snacks.[59] This

approach recognised the importance of the total amount of carbohydrate in the diet, and the effects of this nutrient on post-prandial blood glucose but allowed some flexibility of food choices within this fixed allowance. Carbohydrate exchanges remained popular, primarily amongst people with T1DM, and similar approaches are used today, although their purpose is to allow flexibility in insulin dose adjustment and patients are rarely prescribed a fixed number of exchanges (now referred to as 'carbohydrate portions').[60]

A move away from specific quantities of carbohydrate began in the UK in the 1980s when the British Diabetic Association (now known as Diabetes UK) released their first position statement on diet and diabetes, where the focus was on high fibre sources of carbohydrates and the exclusion of mono- and di-saccharides (sugars) "*wherever possible except in cases of illness or hypoglycaemic emergency*".[61] Only in the context of the recommendation to reduce fat intake is it acknowledged that carbohydrate may make up "*half or more*" of dietary energy, suggesting a stance towards increasing unrefined carbohydrate foods. These guidelines became known as the 'healthy eating' approach to diet and diabetes, suggesting there was no need for a special 'diabetic diet' that differs much from that which the general population should consume.[59] The update of this statement in 1992 [62] made a more specific recommendation that 50-55% of dietary energy should be derived from carbohydrate, promoting foods high in fibre and allowing up to 25g of added sugars per day, thereby continuing to recommend a 'healthy eating' approach but with more specific guidance around quantities of carbohydrate and sugars.

European, American and British dietary recommendations for diabetes were issued in quick succession between 2003 and 2004.[1,63,64] There was broad consensus amongst these

guidelines that carbohydrate should form 45-60% of total energy, a range which includes higher intakes than those recommended to the general population at the time, and since (50% of energy).[65]

By 2008 the ADA guidelines [66] had removed any specific recommendations for the quantity of carbohydrate and UK guidelines followed suit with their update in 2011.[2] A further update of the ADA guidelines in 2014 [47] and the UK guidelines published in March 2018 [52] both remain unchanged in this respect, with the UK guidelines specifically taking a food-based approach to their recommendations and suggesting a range of effective dietary approaches rather than focussing on specific nutrients such as carbohydrate. This reflects the large body of evidence, including systematic reviews, which have failed to demonstrate superiority of any level of carbohydrate intake in managing blood glucose over the long term in T2DM. It is of note that previous recommendations about the specific quantity of carbohydrate, or the proportion of dietary energy that should be derived from carbohydrate, were based on the consensus of expert opinion rather than sound scientific evidence.

The lack of evidence regarding the quantity of carbohydrate in T2DM may be responsible for the variation in practice amongst dietitians previously reported by the author in one of the only studies of RD practice in this area.[3] However, the broader topics of uncertainty in health care and variation in practice warrant further exploration as they may inform the basis for the development of a framework for a new intervention which could help to minimise unnecessary variation in practice despite a lack of clear evidence. The development of this framework forms part of this thesis and will be outlined in the objectives.

1.6 Uncertainty in health care

The degree of certainty of the effectiveness of any given intervention, or indeed which intervention to choose, can be expressed or interpreted in several ways. A useful description of the various levels of certainty and their relation to the level of knowledge is provided by Djulbegovic *et al;* [67] who refer to a 'perfect state of knowledge' and a 'reducible uncertainty' which are distinct from, although can be related to, statistical uncertainty (Figure 1).

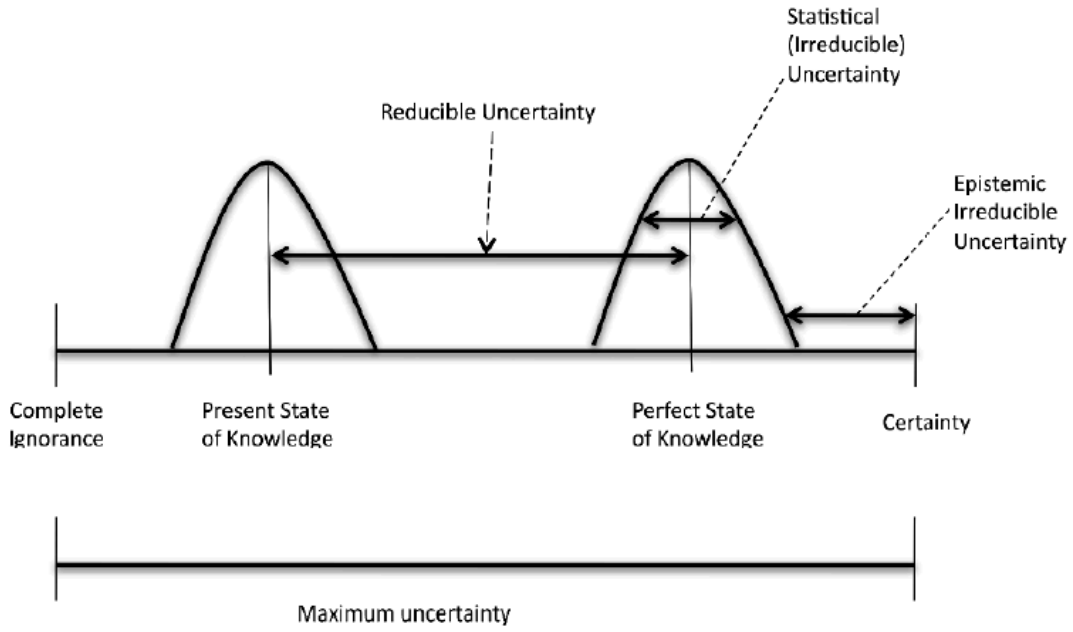


Figure 1 – Relationship between knowledge and uncertainty [67]

In any scientific endeavour, the goal is to shrink the reducible uncertainty and, through methodological rigour, to minimise the statistical uncertainty. Within Djulbegovic's taxonomy of uncertainty,[67] that which applies to this thesis relates not to epistemic or even statistical uncertainty, but to a category described as 'Subjective Uncertainty'; more specifically under three of the potential sub-types:

1. Conflicting Evidence.

2. Degree of beliefs, values and preferences.
3. Disagreement.

Several recent systematic reviews have demonstrated there is no shortage of published research in the field of carbohydrate quantity and T2DM.[54,68,69] It is also clear that much of that evidence fails to answer the question of how much carbohydrate people with T2D should consume. Some differences in conclusions could be accounted for by the researchers' methodological decisions or inadequacies, or by the statistical uncertainty inherent in all trials of interventions or meta-analyses thereof. However, when these individual trials are pooled in the form of meta-analyses, provided the methods are rigorous and heterogeneity is acknowledged and accounted for, the overall effect represents the most accurate estimate of an outcome that research can offer.[70] In the case of quantity of carbohydrate in T2DM, this estimate remains uncertain. This could therefore be argued to fall under sub-type (1) 'Conflicting evidence'.

Djulbegovic's sub-types (2) and (3) are somewhat related in that one is often the precursor to the other. They occur in the absence of evidence or when bias is overlooked, findings ignored or over-inflated or when other interests take precedence. The combination of these three types of uncertainty in the field of carbohydrate and T2DM goes beyond the over-simplified and often false binary choice that might be presented in a case of clinical equipoise and leads to a less reasoned approach. It could be, as proposed by Howell & Burnett [71] that existing knowledge often biases acquisition of the new evidence and that confirmation bias acts as a barrier to reducing uncertainty in areas where there is a large volume of conflicting evidence.

There are a multitude of reasons for practice variation in health care, including gaps in the evidence-base, leading to uncertainty.

1.7 Practice Variation

Variations in the practice of health care professionals exist in a range of fields and a wide range of contributing factors have been cited, ranging from the structure of care and the availability of resources [67] or the geographical location of the patient, to the culture of healthcare professionals' workplaces and their access to, or knowledge and skills in finding and using, evidence to support their practice.[72] It is expected that some of these factors will influence dietitians' practice in giving carbohydrate advice to patients with T2DM, however, it has been proposed that the greatest reason for practice variation in medicine remains uncertainty as described in the previous section, or even ignorance.[67,73] Clinical guidelines are frequently used to inform practice, to reduce uncertainty or practice variation and to avoid ignorance, but not all guideline recommendations are evidence-based, as scientific evidence does not always exist in order to answer the clinical questions.[74] Even guidelines intending to be evidence-based must address areas of uncertainty or where there is a lack of evidence, after which remains the challenge of dissemination of those guidelines to clinicians in order to change their behaviour and evidence suggests that traditional passive means are largely ineffective.[75]

1.8 Evidence-Based Medicine (EBM) vs Guideline-Based Medicine

Alpert [74] indicates that expert opinion forms the basis of many guideline recommendations, which are therefore influenced by beliefs, values and preferences of those involved in setting the consensus recommendations. In other words, they risk being biased and not entirely

evidence-based. Previous nutrition guidelines in diabetes recommending a specific proportion of dietary energy to be derived from carbohydrate have not been based on evidence, but on expert consensus and extrapolated from data regarding general population guidelines, the numerical justification for which has also not previously been well elucidated.[76] It could be argued this method for developing guideline recommendations lacks rigour and will subsequently suffer from the undue influence of group or individual, perhaps even unconscious, biases. Knaapen [77] emphasises the importance of transparency in the absence of evidence, and the process of searching for and assessing the quality of the evidence as important in being evidence-based.

Qualitative research methods have the potential to inform guideline development where there is a lack of clear quantitative evidence, by enhancing understanding of the patients' and professionals' experiences or views, which may in turn have a bearing on their implementation or applicability. However, such methods are largely overlooked in clinical guidelines due to the current hierarchy of research evidence under which most guidelines traditionally operate.[78] Their potential role in contributing to clinical guideline development is therefore likely to be underestimated as the methodology of guideline development will frequently exclude qualitative literature, as in the existing nutrition guidelines for diabetes.[52] Given the importance of the impact of improving diabetes care and patient outcomes, research that improves understanding of the experiences, views and preferences of both patients and healthcare professionals and therefore has the potential to improve how care is delivered, should not be overlooked.[79]

1.9 **Research Aim, Questions & Objectives**.

This research aims to inform the development of Carbohydrate Awareness Advice as an intervention with a clearer definition and framework for delivery. It will use a systematic review and meta-analysis, interviews and focus groups to answer the following research questions. **Figure 2**, below, outlines how each of the research questions and objectives will be achieved.

1. What evidence exists for an optimal quantity of carbohydrate for glycaemic control and weight management in T2DM?
2. How can the delivery of carbohydrate advice, to people with T2DM by dietitians, be improved?
3. What should inform a clearer definition of 'carbohydrate awareness advice' in T2DM?

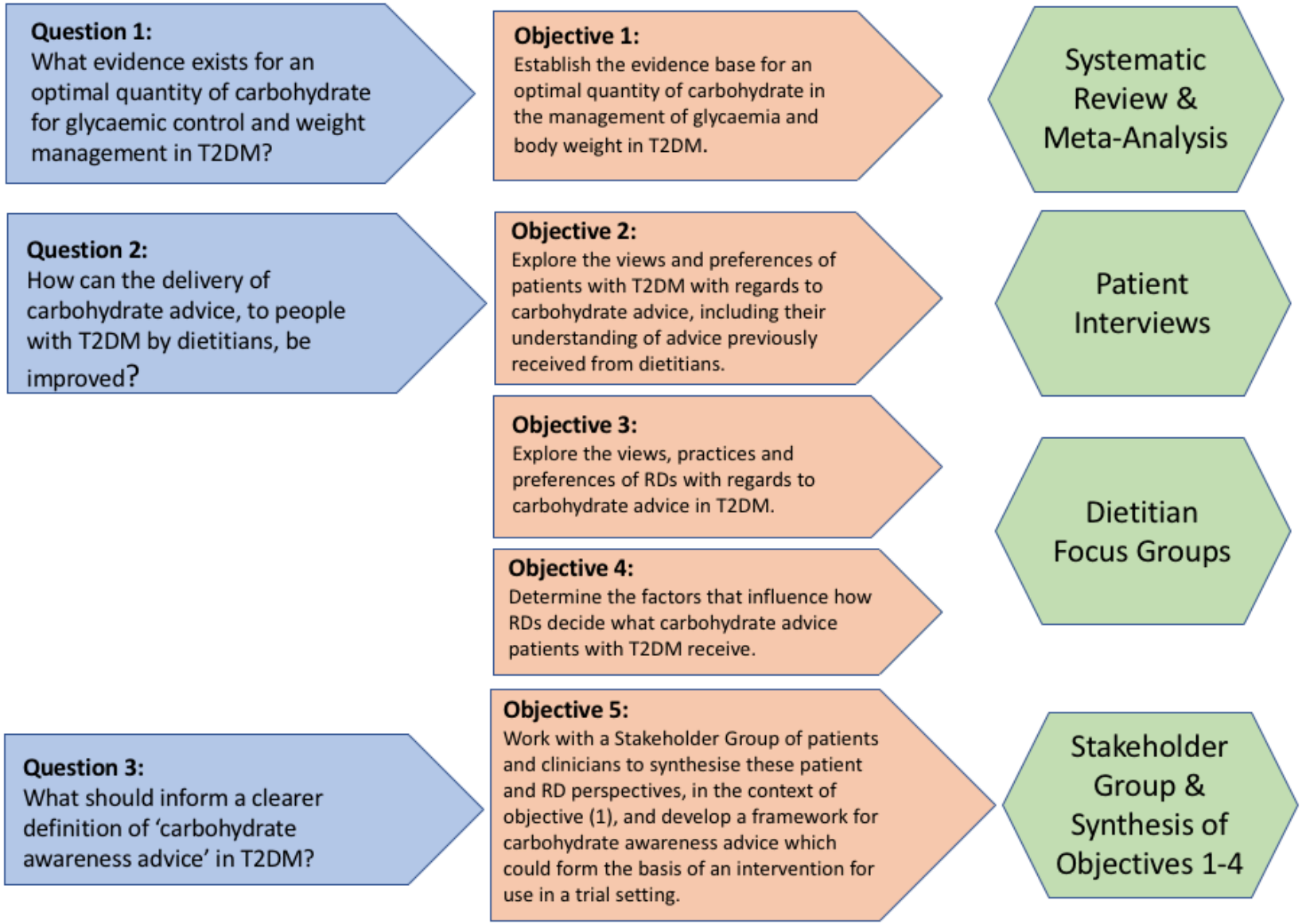
The research **objectives** are:

1. Establish the evidence base for an optimal quantity of carbohydrate in the management of glycaemia and body weight in T2DM.
2. Explore the experience, views and preferences of patients with T2DM with regards to carbohydrate advice, including their understanding of advice previously received from dietitians.
3. Explore the views, practices and preferences of RDs with regards to carbohydrate advice in T2DM.
4. Determine the factors that influence how RDs decide what carbohydrate advice patients with T2DM receive.
5. Work with a Stakeholder Group of patients and clinicians to synthesise these patient and RD perspectives, in the context of objective (1), and develop a framework for

carbohydrate awareness advice which could form the basis of an intervention for use in a trial setting.

As well as improving our understanding of patients' experience of dietetic advice for carbohydrate in T2DM, the outcome of this research will lead to a framework for Carbohydrate Awareness Advice in T2DM. The newly developed framework can then form the basis for an intervention to be tested in future clinical trials against 'standard care' to establish more clearly its role in the dietary management of T2DM. This will allow a more consistent approach that may lead to improved clinical outcomes for people with T2DM.

Figure 2 – Research Questions, Objectives & Methods



1.10 Thesis Structure

The research carried out for this thesis follows the Medical Research Council's guidance for developing and evaluating complex interventions.[80] The guidance was published in 2000 and updated in 2008, with the intention of assisting health researchers to develop more effective interventions.[80] The guidance covers the development, evaluation and implementation of complex interventions and, to follow best practice, this study was planned to follow the first step in the development of interventions, namely:

1. Identifying the evidence base (Chapters 1 & 2)
2. Identifying or developing theory (Chapters 1 & 4 - 6)
3. Modelling process and outcomes (Qualitative Study – Chapters 4 -6)

Therefore, this thesis represents the development and modelling phases of the MRC guidance. Future research might take this work further to include the piloting, feasibility, evaluation and implementation stages, however these phases fall outside the scope of this thesis.

Chapter Two is a comprehensive systematic review and meta-analysis, addressing the question of how much carbohydrate people with T2DM should consume to achieve optimal blood glucose control. The review addresses the primary outcome of HbA1c but also looks at the secondary outcome of body weight, given its importance in the literature in relation to blood glucose management. This Chapter aims to establish the state of evidence for a definitive quantity of carbohydrate and therefore support the need for a clearly defined intervention 'Carbohydrate Awareness Advice', which can address the question of carbohydrate without making specific claims about quantities. It is the most comprehensive

review in the field, encompassing more than 3 decades of research evidence and is presented in paper format.

Chapter Three describes the methods and methodology used to conduct the qualitative part of the study and to collect and analyse the data. It aims to be reflexive by including a commentary of the researcher's experience and approach to the study.

Chapter Four presents the findings from the patient interviews and focus groups with RDs. These are organised into themes and subthemes. The results from the patient interviews and both rounds of focus groups are presented and summarised separately, with a final summary bringing together the overall analysis of the findings.

Chapter Five applies a theoretical model, Kleinman's Explanatory Model,[81] to the results presented in Chapter Four. Explanatory Models and the related concepts offer insight into how patients access health care and how they understand and manage their condition, as well as helping health care professionals to understand the social and cultural aspects of disease. This Chapter also consolidates the work of the Stakeholder Group and the findings presented in Chapter Four to describe a framework for a newly-described intervention in T2DM: Carbohydrate Awareness Advice.

Chapter Six brings together the overall findings and critically discusses the strengths and limitations of the research. It presents the conclusions of the study, assesses whether the study aims and objectives have been met and makes recommendations for further research and policy.

CHAPTER TWO

CARBOHYDRATE RESTRICTION FOR GLYCAEMIC CONTROL IN TYPE 2 DIABETES: A SYSTEMATIC REVIEW & META-ANALYSIS

This Chapter has been published as a paper in Diabetic Medicine and the citation below applies to the entire chapter. It is presented in the format of the version published in Diabetic Medicine.

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Systematic Review or Meta-analysis

Carbohydrate restriction for glycaemic control in Type 2 diabetes: a systematic review and meta-analysis

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Abstract

Aim To conduct a systematic review and meta-analysis to evaluate the effect of carbohydrate restriction on glycaemic control in Type 2 diabetes.

Methods We searched Medline, EMBASE and CINAHL for the period between 1976 and April 2018. We included randomized controlled trials comparing carbohydrate restriction with a control diet which aimed to maintain or increase carbohydrate intake, and that reported HbA_{1c} as an outcome and reported the amount of carbohydrate consumed during or at the end of the study, with outcomes reported at ≥3 months.

Results We identified 1402 randomized controlled trials, 25 of which met the inclusion criteria, incorporating 2132 participants for the main outcome. Definitions of low carbohydrate varied among the studies. The pooled effect estimate from meta-analysis was a weighted mean difference of –0.09% [95% CI –0.27, 0.08 (P = 0.30); I^2 72% (P <0.001)], suggesting no effect on HbA_{1c} of restricting the quantity of carbohydrate. A subgroup analysis of diets containing 50–130 g carbohydrate resulted in a pooled effect estimate of –0.49% [95% CI –0.75, –0.23 (P <0.001); I^2 0% (P = 0.56)], suggesting a clinically and statistically significant effect on HbA_{1c} in favour of low-carbohydrate diets in studies of ≤6 months' duration.

Conclusions There was no overall pooled effect on HbA_{1c} in favour of restricting carbohydrate; however, restriction of carbohydrate to 50–130 g per day had beneficial effects on HbA_{1c} in trials up to 6 months. Future randomized controlled trials should be of >12 months' duration, assess pre-study carbohydrate intake, use recognized definitions of low-carbohydrate diets and examine reasons for non-adherence to prescribed diets in greater detail.

Diabet. Med. 36, 335–348 (2019)

Introduction

Diabetes affects an estimated 4.5 million people in the UK and 425 million people globally, with Type 2 diabetes accounting for ~90% of cases [1,2]. In the UK Prospective Diabetes Study, each 11-mmol/mol (1%) reduction in HbA_{1c} was associated with a 21% risk reduction for any endpoint and a 37% risk reduction for macrovascular complications [3]. Nutrition therapy interventions have been shown to reduce HbA_{1c} by up to 22 mmol/mol (2.0%) [4] and there is significant current interest in the role of dietary carbohydrates for weight control and in the context of Type 2 diabetes for the control of glycaemia; however, the ideal amount of dietary carbohydrate remains unclear. Current US and European diabetes organizations do not make strong recommendations about the quantity of carbohydrate, but rather state that monitoring of total carbohydrate is a key strategy in achieving glycaemic control, with the focus on dietary changes instead targeted at weight loss in those who are overweight [5–7]. The average proportion of energy obtained from carbohydrate in the UK general population is 47%, and it is estimated a similar amount of carbohydrate is consumed in people with Type 2 diabetes [8].

Several reviews considering the binary options of low- or high-carbohydrate diets have produced mixed results, probably as a result of methodological differences and poor dietary adherence in included trials [9–12]. Recent meta-analyses of low-carbohydrate diets have consistently found a small but significant reduction in HbA_{1c} in the pooled effect at 6 months that was no longer present at 12 months,

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What's new?

- A large number of trials and systematic reviews have obtained conflicting results regarding the effect of restricting carbohydrate on glycaemic control.
- The present study includes analysis of trials reporting adherence to carbohydrate-restricted diets, showing this has no material impact on the outcome and bringing the evidence up to date by including more recent trials.
- Clinicians should inform people with Type 2 diabetes that there are a number of effective dietary approaches for improving glycaemic control, which may include restricting carbohydrate to 50–130 g per day.

supporting the conclusions made in earlier reviews [12–14]. Another recent review found modest reductions in HbA_{1c} were present at 12 months [15]. Research by van Wyk *et al.* [9] highlighted the difficulty people find in adhering to prescribed diets, showing just an 8-g/day difference in the carbohydrate content of diets between study arms at the end of the studies. Recent reviews have acknowledged the issue of adherence, but none has performed subgroup analyses on trials demonstrating dietary adherence to establish the impact of this on the primary outcome. The search period of the most recent review of carbohydrate intake in people Type 2 diabetes did not include the latest randomized controlled trials (RCTs) published [16]. There is also an increasing interest in the use and effectiveness of dietary carbohydrate restriction for managing diabetes and weight. These factors underline the need for a good-quality synthesis of the evidence in this area. The aim of the present review, therefore, was to provide an updated evaluation of the impact of carbohydrate restriction on glycaemic control in adults with Type 2 diabetes, including the most recently published research and with an additional focus on trials demonstrating dietary adherence.

Methods

Data sources and searches

The present systematic review and meta-analysis was conducted with reference to the Cochrane Handbook for Systematic Reviews of Interventions [17] and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [18]. A protocol was published and registered with PROSPERO in advance [19].

The search dates were restricted to 1976 onwards (because of the introduction of HbA_{1c} measurement at this time [20]) and the databases were searched up to April 2018. Databases searched included Medline (1976 to April 2018), EMBASE (1980 to April 2018) and CINAHL (1982 to April 2018). Databases of ongoing trials, the Cochrane Library and DARE, dissertations and theses, and other grey literature were also searched. Search terms and the search strategy were developed by the research team and search results were independently reviewed by P.D.M. and S.K.R. Summary data were sought and data extraction was carried out by P.D.M., verified by S.K.R., with any conflicts over inclusion resolved by discussion.

Study selection

Studies were eligible for inclusion if they were RCTs including adults diagnosed with Type 2 diabetes, had a minimum intervention duration of 8 weeks and reported outcomes at a minimum of 12 weeks, and if the intervention restricted the proportion or quantity of dietary carbohydrate. Studies using active control diets were included, but not if the control diet included carbohydrate restriction in comparison to the intervention diet. Studies were not grouped according to the type of control diet and all forms of control diet that did not include carbohydrate restriction were permitted, including low-fat, high-carbohydrate, low-glycaemic index, high-protein, Mediterranean and 'healthy eating'. Included studies also needed to report actual (self-reported or measured) carbohydrate intake during or at the end of the intervention and HbA_{1c} as an outcome measure. All countries, languages and settings were eligible.

Data extraction and quality assessment

Data extraction was carried out by P.D.M., verified by S.K.R., with any conflicts over inclusion resolved by discussion. Data were extracted to a purposely designed spreadsheet by P.D.M. and checked by S.K.R. Data items included: study and participant characteristics (including duration, setting, ethnicity, age, sex); details of the intervention and control diets (including macronutrient composition prescribed, other dietary advice given); outcome data for HbA_{1c}, weight, blood pressure and lipids; and details of retention rates and dietary adherence, where available. Risk of bias was assessed according to the Cochrane Handbook for Systematic Reviews of Interventions [17] at study level and entered into Review Manager 5.3 [21].

Data synthesis and analysis

Means and standard deviations (or standard error) were used to conduct meta-analyses for the primary outcomes HbA_{1c} and body weight using a random-effects model, and to compare interventions using weighted mean difference (WMD) and 95% CIs. For RCTs in which people with diabetes were part of a larger cohort including participants without diabetes, if separate data were not reported, authors were contacted to request the relevant values for

only the participants with Type 2 diabetes. Additional or missing data were obtained from four of the five authors contacted [22–25] and, where they were not available, the study was not included in the meta-analysis. Data for the overall meta-analyses were taken from the longest available time point for each included study. Two studies did not report data for body weight and were therefore excluded from the meta-analysis [25,26]. Comparison of the carbohydrate quantity of intervention diets was in absolute grams of carbohydrate, rather than % of total energy, to allow direct and accurate comparison. For RCTs in which only the percentage of total energy from carbohydrate was reported, a conversion was made using 4 kcal per 1 g carbohydrate, based on the mean reported energy (calorie) intake for each study, or based on an estimated calorie intake of 2000 kcal if these data were not available [27]. This level of calorie intake has been used by other researchers for conversion to grams of carbohydrate [14,28] and is similar to or greater than the amounts reported in trials included in this review (Table 1). The RCTs included in the present review reported HbA_{1c} values as DCCT-aligned (%) [29] rather than the newer International Federation of Clinical Chemistry-standardized concentrations [30] and these were used in the present review without conversion to avoid potential errors. Heterogeneity in the sample of studies was assessed using the I^2 statistic and the significance of the associated chi-squared value ($P<0.05$).

Subgroup analysis

Subgroup analysis based on levels of carbohydrate intake were conducted to elicit differences in the key outcomes between groups of carbohydrate intake. Level descriptors of carbohydrate intake proposed by Feinman *et al.* [28] have been widely adopted in the field of carbohydrate research and were used to define the subgroups in this meta-analysis. Only two studies [31,32] met the definition of 'high' carbohydrate and therefore this group was collapsed with the 'moderate' category to form a group named 'moderate+' in this analysis. A further subgroup analysis was undertaken to achieve a key aim of the present study: a meta-analysis of a subset of included studies demonstrating dietary adherence. Adherence to the study diet was defined for this purpose as ±10% of the prescribed carbohydrate (g) in the restricted carbohydrate group. Heterogeneity within each subgroup was examined as well as the overall I^2 value, and a test for heterogeneity between subgroups was also performed.

Results

Search results

The selection of studies is shown in a flow diagram in Fig. 1, in accordance with the PRISMA guidelines [18]. Initial database searches yielded 1402 articles, and 72 full-text articles were retrieved before eligibility could be established. A total of 25 studies met the inclusion criteria.

Study characteristics and risk of bias

The characteristics of the 25 included RCTs are summarized in Table 1, grouped according to dietary intervention using the definitions of levels of carbohydrate prescribed and outlined in Table 2.

The publication period covered 36 years and ranged from 1981 to 2017. Study duration ranged from 12 to 208 weeks, with a mean duration of 55 weeks. The majority of studies lasted longer than 26 weeks, with seven studies lasting longer than 52 weeks. All except one study in the low-carbohydrate category lasted for ≤26 weeks and, although that study was 104 weeks in duration, it only reported outcomes at 26 weeks [24]. Study sample sizes ranged from 12 [22] to 419 [33] and a total of 2132 participants were included in this review. Of the 25 included studies, 10 of the dietary interventions met the definition of moderate carbohydrate (n= 1111).

Figures 2 and S1 show the risk of bias across all studies. The principal risk of bias stemmed either from the poor description of the randomization sequence and allocation concealment or from there being no description of the pre-study dietary intake of participants ('other bias'). This represented more than one-third of studies included in the present review.

Glycaemic control

The baseline and post-intervention values for HbA_{1c}, weight, total cholesterol and blood pressure are shown in (Tables 3 and S1). Blood pressure and lipids were not routinely included as outcomes or reported in the studies included and were not the main focus of the present review.

Significant between-group differences in HbA_{1c} were observed in six of the 25 RCTs [34–39]. Some studies reported significant differences at 6 months which were not maintained at 12 months and beyond [24,33]. Meta-analyses conducted for HbA_{1c} for all studies found no overall effect of modifying carbohydrate and demonstrated a high level of heterogeneity [WMD –0.09% (95% CI –0.27, 0.08; P = 0.30); I^2 72% (P <0.001); Fig. 2]. Subgroup analysis of studies meeting the definition of very low carbohydrate (<50 g per day) also found no overall effect, with very low levels of heterogeneity observed [WMD –0.13% (95% CI –0.34, 0.08; P = 0.28); I^2 19% (P = 0.28)]. Analysis of the subgroup of five low-carbohydrate diet studies (50–130 g per day) showed a statistically and clinically significant result in favour of the intervention diet [WMD –0.49% (95% CI –0.75, –0.23; P < 0.001); I^2 0% (P = 0.56)]. All studies in this

Table 1 Study characteristics

Author, year	*n*	Duration, weeks	Age, years	Men, %	Ethnicity	Setting	Intervention diet[d] (restricted carbohydrate), carbohydrate g/day	Control diet
Very low carbohydrate								
Ben-Avraham, 2009 [25]	46	104	52	86	NR	Israel, workplace clinic	20 g for 2 months, then rising to 120 g	Low-fat, calorie-restricted Mediterranean, calorie-restricted
Davis, 2009 [62]	105	105	54	18	62% black	USA, Research Centre	20–25g, increased in 5-g increments	Low-fat (25% of energy)
Dyson, 2007[a] [22]	12	12	52	23	NR	UK, Hospital Outpatients	< 40 g	Healthy eating (reduced fat and saturated fat, low-glycaemic- index)
Goldstein, 2011 [63]	52	52	57	48	NR	Israel, Hospital Outpatients	25 g for 6 weeks, increasing to 40 g	ADA 2011 guidelines* 'restricted calorie'
Iqbal, 2010[a] [26]	144	104	60	84[b]	63% African-American[c]	USA, Hospital Outpatients	30 g	Low-fat, AHA guidelines**
Salsow, 2017	19	32	55	43	60% white	Online, USA	20–50 g very-low-carbohydrate ketogenic	ADA guidelines, low-fat
Tay, 2015 [50]	115	52	58	64	NR	Australia, Research Centre	< 50 g	High-carbohydrate (53% energy) and low-glycaemic-index
Westman, 2008 [64]	97	24	52	24	58% white	USA, Outpatient Research Centre	20 g	Low-glycaemic-index (55% energy from carbohydrate)
Low carbohydrate								
Daly, 2006 [41]	102	12	58	48	NR	UK, Hospital Outpatients	70 g	Healthy eating, reduced fat
Jonasson, 2014	61	104	62	44	NR	Sweden, Primary Care	90 g[f]	Low-fat (30% energy from fat)
Jönsson, 2009 [34]	13	25	64	77	NR	Sweden, Primary Care	Unclear	Diabetes diet (healthy eating)
Sato, 2017 [35]	66	26	58	76	NR	Japan, Outpatients	130g	Calorie-reduced diet (28 kcal per kg body weight), 50–60% energy from carbohydrate
Yamada, 2014 [36]	24	26	63	50	NR	Japan, Outpatients	70–130 g	Japanese Diabetes Association guidelines, 50% energy from carbohydrate
Moderate+ carbohydrate								
Brehm, 2009 [65]	52	52	56.5	37	75% white	USA, Outpatients	174 g[g]	High-carbohydrate (60% energy from carbohydrate)
De Bont, 1981 [46]	136	26	54	0	NR	UK, Hospital Outpatients	146 g[h]	Low-fat (30% energy from fat)
Elhayany, 2010 [38]	259	52	56	51	NR	Israel, Primary Care	194 g[i]	Healthy eating, low-glycaemic- index (50–55% energy from carbohydrate)
Esposito, 2009[e] [39]	215	208	52	50	NR	Italy, Hospital Outpatients	225 g[j]	Low-fat (AHA guidelines)
Krebs, 2012 [33]	419	104	58	40	84% European	New Zealand, Outpatients	138 g[k]	Low-fat, high-carbohydrate (55% energy from carbohydrate)
Larsen, 2011 [23]	99	52	59	48	NR	Australia, Diabetes Centre	153 g[l]	High-carbohydrate (55% energy from carbohydrate)
Milne, 1994 [43]	64	78	59	55	NR	New Zealand, unclear	160 g[m]	High-carbohydrate (55% energy from carbohydrate)
Barakatun Nisak, 2013[e] [32]	104	12	56	37	53% Malay	Malaysia, Outpatient Clinic	232 g[n]	Low-glycaemic-index (50–60% energy from carbohydrate)
Parker, 2002 [47]	54	12	61	35	NR	Australia, Outpatient Clinic	167 g[o]	Low-protein (60% energy from carbohydrate)
Walker, 1995 [44]	24	16	58	38	NR	Australia, unclear	160 g[p]	Low-fat, high-carbohydrate (59% energy from carbohydrate)

Table 1 (*Continued*)

Author, year	*n*	Duration, weeks	Age, years	Men, %	Ethnicity	Setting	Intervention diet[d] (restricted carbohydrate), carbohydrate g/day	Control diet
Watson, 2016 [51]	61	24	55	54	NR	Australia, unclear	128 g[q]	Low-fat, high-carbohydrate (51% energy from carbohydrate)
Wolever, 2008 [45]	162	52	60	54	NR	Canada, Outpatients	188 g[r]	High-glycaemic-index

ADA, American Diabetes Association (Dietary Recommendations); AHA, American Heart Association; NR, not reported.
[a]Demographic data based on entire cohort or modified-carbohydrate group only, with significant between-group differences noted below.
[b]Statistically significantly more women in low-carbohydrate-diet group at baseline.
[c]Statistically significantly more African-American people in low-carbohydrate-diet group at baseline.
[d]Carbohydrate for prescribed diet. If not directly reported, this has been calculated using information available in the manuscript, e.g. baseline calorie intake, with specific examples detailed below.
[e]Met the definition for 'high-carbohydrate' but included in 'Moderate+' group.
[f]Based on 20% energy, for 1800 kcal/day. [g]Based on 45% energy, for 1,550 kcal/day. [h]Based on 40% energy for 1460 kcal/day. [i]Based on 35% of 2221 kcal/day. [j]Based on 50% of 1800 kcal/day. [k]Based on 40% of 1378 kcal/day. [l]Based on 40% of 1529 kcal/day. [m]Based on 45% of 1419 kcal/day. [n]Based on 55% of 1686 kcal/day. [o]Based on 42% of 1587 kcal/day. [p]Based on 40% of 1601 kcal/day. [q]Based on the mean of 33% of 1434–1673 kcal/day. [r]Based on 39% of 1930 kcal/day.

subgroup were of ≤6 months' duration, or only reported outcomes at 6 months.

Baseline HbA_{1c} amongst the study groups ranged from 43 mmol/mol (6.1%) to 87 mmol/mol (10.1%), with some studies specifically excluding participants with poorly controlled blood glucose and others adopting the opposite strategy.

Body weight

Changes in body weight or BMI were included in the majority of studies, but body weight outcomes were not available for two studies which were therefore excluded from the meta-analysis [25,26]. Two studies [36,40] reported a sample with near-healthy weight and BMI at baseline. Significant between-group differences in body weight were observed in just five of the 25 included studies, three of which were from the subgroup of low-carbohydrate diets. No overall effect on weight was observed in the meta-analyses for any of the studies [WMD –0.13 kg (95% CI –0.33, 0.08; P = 0.22); I^2 78% (P <0.001); Fig. S1]. A high level of heterogeneity was observed in the pooled meta-analysis but not in the low-carbohydrate subgroup. This subgroup showed a statistically significant pooled effect in favour of restricted carbohydrate [WMD –0.43 kg (95% CI –0.74, –0.12; P = 0.006); I^2 24% (P = 0.26)].

Blood pressure and blood lipids

Of the 25 studies, 11 did not fully report outcomes for blood pressure and, in those that did, changes were unremarkable and rarely reached statistical significance. Such differences between groups were seen only in the paper by Jönsson *et al.* [34].

Complete blood lipid outcomes were reported in 17 of the 25 studies. Statistically significant differences between groups were seen in just seven of the studies and the most commonly observed difference was a greater increase in HDL cholesterol in the modified-carbohydrate group.

Study diets, dietary assessment and adherence

The amount of carbohydrate that participants were instructed to consume within the 'moderate+' group ranged from 138 g per day to 231 g per day (or 138 g to 194 g if the two 'high' carbohydrate studies are excluded). Half the studies included in the present review did not report or record the baseline carbohydrate intake of participants (Table S2). Several trials in the moderate group described the interventions as 'low-carbohydrate' at a prescribed level based on 40% of total energy intake. Adherence to study diets was observed more frequently in the moderate+ group than in other groups.

Thirteen studies reported relative adherence to the prescribed carbohydrate intake in the intervention arm (± 10%

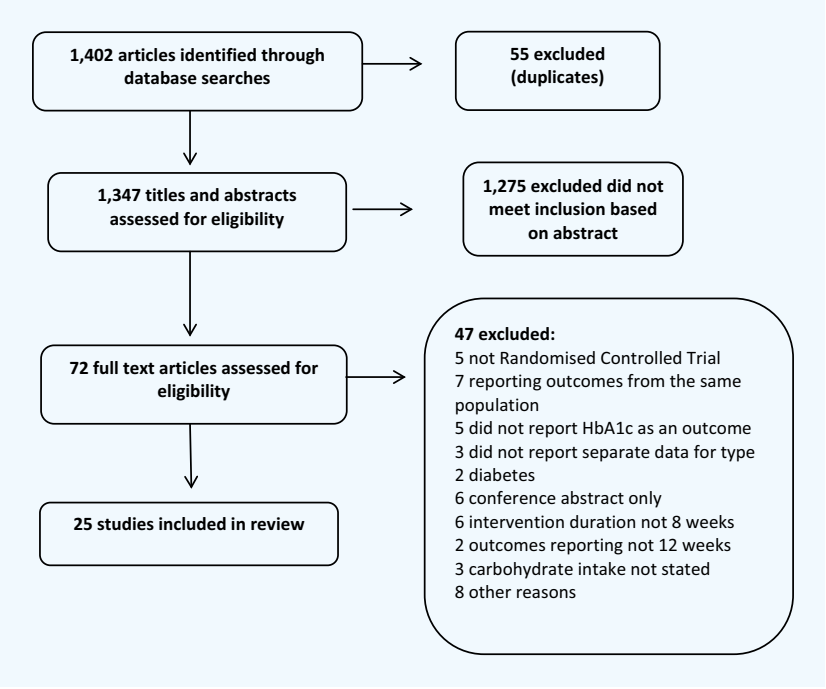

FIGURE 1 Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram. RCT, randomized controlled trial.

Table 2 Definitions of levels of carbohydrate

	Carbohydrate g/day	Carbohydrate % of energy*	Number of studies (*n*)
Very-low carbohydrate	20–50	6–10	8 (467)
Low carbohydrate	<130	<26	5 (239)
Moderate carbohydrate	130–225	26–45	10 (1111)
High carbohydrate	>225	>45	2 (315)

*Based on 2000-kcal diet.

in grams of carbohydrate). A further subgroup analysis of the effect on the primary outcome using only these studies showed no impact on overall carbohydrate restriction [WMD –0.06 (95% CI –0.15, 0.02; P = 0.16); I^2 88% (P < 0.01); Fig. S2]. Of these 13 studies, 10 were within the 'moderate+' group of carbohydrate restriction, two were 'low-carbohydrate' and one was in the 'very-low-carbohydrate' group. The mean (range) average carbohydrate intake in the intervention group of the 13 studies was 150 (41–209) g, (median 166 g) and the control diets were mostly low-fat, high-carbohydrate diets in this group.

A variety of methods for dietary measurement was used in the individual studies, ranging from a 24-h recall, food frequency questionnaires or 7-day weighed food records, to smartphone apps, such as MyFitnessPal. Several studies did not describe how the dietary assessment was carried out [31,36,42].

Discussion

The present systematic review and meta-analysis of carbohydrate restriction for glycaemic control in Type 2 diabetes has shown no significant overall effect on HbA_{1c} or body weight. Current national nutrition guidelines for Type 2 diabetes reflect this and do not make a specific recommendation with regard to the quantity of carbohydrate that should be consumed [5–7].

A small and clinically significant reduction of 5 mmol/mol (0.49%) in HbA_{1c} was seen in the subgroup of studies using 50–130 g carbohydrate per day. These studies were ≤6 months in duration, or only reported outcomes at 6 months, an important limitation to the clinical application of this finding. Earlier reviews found that reductions in HbA_{1c} or weight at 3 or 6 months were not maintained beyond 12 months [10,12–14]. Adherence to the prescribed diets in this group was good and may be an important factor in the

positive result seen in the meta-analysis, but if this success cannot be replicated in longer trials or using even greater restrictions in carbohydrate, then this is an important limitation with implications for future research and clinical practice.

Eight other meta-analyses published in the last 5 years address a similar research question to that of the present review and their findings are summarized in Table 4. The lack of agreement amongst these meta-analyses is attributable in part to differences in the methodology, such as the inclusion criteria or the approach taken in the meta-analysis. Several reviews obtained similar findings to those of the present review [12,14,42], while Snorgaard *et al.* [12] found that the greatest improvements in HbA_{1c} were associated with the greatest reductions in carbohydrate, a finding which is not replicated in the present review.

Several methodological limitations are present in the RCTs included in the present review, specifically, the lack of isocaloric study arms, the varied methods of dietary assessment, differences in baseline glycaemic control of study participants, a lack of adherence to the study diet, and differences in study protocols for adjustment of diabetes medication.

Improvements in HbA_{1c} are regularly seen in both groups in included studies and may be related to a reduction in energy intake and subsequent weight loss across the entire study population. With some exceptions [23,24,33], most studies did not intend to keep the amount of dietary energy between study arms equal, and therefore results may have been confounded by differential changes in weight as a result of differing energy intakes between study groups. Caution should be exercised in interpreting these outcomes in the

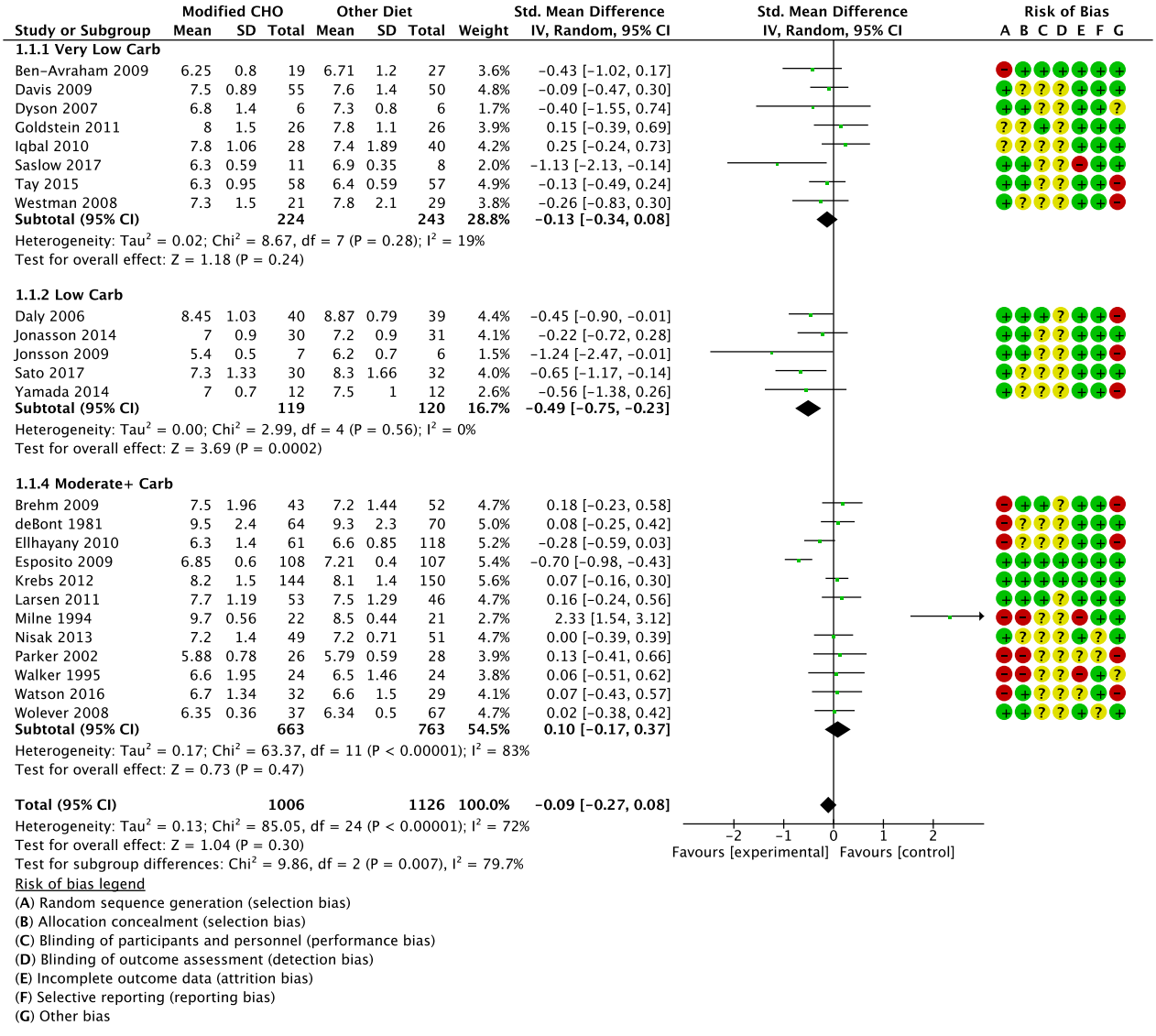

FIGURE 2 Forest Plot for HbA_{1c}. SD, standard deviation; df, degrees of freedom.

Table 3 Results of individual studies: HbA_{1c} and weight

	Baseline				Post-intervention			
	Modified-carbohydrate		Control/Other diet		Modified-carbohydrate		Control/Other diet	
Author, Year	HbA_{1c}. %	Weight. kg	HbA_{1c}. %	Weight. kg	HbA_{1c}. %	Weight. kg	HbA_{1c}. %	Weight. kg
Very low carbohydrate								
Ben-Avraham, 2009[b] [25]	7.16 (1.28)	87.9 (12.71)	7.16 (1.28)	87.9 (12.71)	6.26 (0.8)	NR	6.71 (1.2)	NR
Davis, 2009[c] [62]	7.5 (1.5)	93.6 (18)	7.4 (1.5)	101 (19)	7.5 (*0.89*)	90.5[a] (*4.8*)	7.6 (*1.4*)	97.9[a] (*5.8*)
Dyson, 2007 [22]	7.2 (1.7)	99.7 (14.6)	7.5 (1.0)	96.9 (12.9)	6.8 (1.4)	91.7 (12.0)	7.3 (0.8)	96.1 (13.8)
Goldstein, 2011[d] [63]	9.0 (1.7)	91.7 (10.2)	8.8 (1.2)	92.2 (13.7)	8.0 (*1.5*)	88.3 (*4.0*)	7.8 (*1.1*)	86.8 (*5.7*)
Iqbal, 2010[e] [26]	7.9 (1.7)	118.3 (21.3)	7.6 (1.3)	115.5 (16.7)	7.8 (*0.2*)	116.8	7.4 (*0.3*)	115.3
Saslow, 2018[f] [54]	7.1 (0.4)	109.7 (24.9)	7.2 (0.3)	90.9 (16.4)	6.3[a]	97.0[a]	6.9[a]	87.9[a]
Tay, 2015[g] [50]	7.3 (1.1)	101.7 (14.4)	7.4 (1.1)	101.6 (15.8)	6.3	92.0	6.4	91.4
Westman, 2008 [64]	8.8 (1.8)	105.5 (19.5)	8.3 (1.9)	106.3 (20.1)	7.3 (1.5)	97.3 (17.6)[a]	7.8 (2.1)	98.3 (20.3)[a]
Low carbohydrate								
Daly, 2006[h] [41]	9.0 (0.20)	101.6 (1.84)	9.1 (0.17)	102.3 (2.49)	8.45 (*0.17*)	98.0 (*0.63*)[a]	8.87 (*0.13*)	101.4 (*0.4*)[a]
Jonasson, 2014[i]	7.4 (0.8)	91 (19)	7.3 (0.8)	99 (21)	7.0 (0.9)	88 (19)	7.2 (0.9)	94 (21)
Jönsson, 2009 [34]	6.2 (0.2)	82.0 (13)	6.9 (0.7)	92.0 (20)	5.7 (0.7)[a]	81.0 (13)[a]	5.9 (0.9)[a]	84.0 (15)[a]
Sato, 2017[j] [35]	8.0	74.0	8.3	73.6	7.3[a]	69.9[a]	8.3[a]	73.8[a]
Yamada, 2014 [36]	7.6 (0.4)	67.0 (15.9)	7.7 (0.6)	68.1 (7.7)	7.0 (0.7)[a]	64.4 (14.2)	7.5 (1.0)[a]	66.7 (7.0)
Moderate+ carbohydrate								
Brehm, 2009[k] [65]	7.4 (0.1)	103.7 (2.8)	7.2 (0.1)	102.1 (2.0)	7.5 (0.3)	99.7 (3.0)	7.2 (0.2)	98.3 (2.0)
de Bont, 1981[l] [46]	10.1 (2.4)	73 (16)	10.0 (2.3)	72 (15)	9.5 (2.4)	70.3 (12.7)	9.3 (2.3)	70.3 (11.4)
Elhayany, 2010[m] [38]	8.3 (1.0)	86.7 (14.3)	8.3 (0.8)	87.8 (13.7)	6.3 (1.4)[a]	77.8 (13.1)	6.6 (0.85)[a]	79.1 (11.6)
Esposito, 2009[n] [39]	7.75 (0.9)	86.0 (10.4)	7.71 (0.9)	85.7 (9.9)	6.85 (*0.6*)[a]	82.2 (*2.0*)	7.21 (*0.4*)[a]	82.5 (*1.9*)
Krebs, 2012[o] [33]	8.1 (1.2)	103.4 (19.7)	8.0 (1.2)	101.9 (20.1)	8.2 (1.5)	99.5 (17.2)	8.1 (1.4)	95.9 (17.1)
Larsen, 2011[p] [23]	7.89	94.6	7.78	95.5	7.7 (1.19)	92.4 (14.49)	7.5 (1.29)	93.3 (12.87)
Milne, 1994 (SE)[q] [43]	9.8 (0.65)	83.1 (3.6)	8.7 (0.49)	80.8 (1.7)	9.7 (0.56)	82.1 (3.2)	8.5 (0.44)	80.7 (3.0)

Table 3 (*Continued*)

	Baseline				Post-intervention			
	Modified-carbohydrate		Control/Other diet		Modified-carbohydrate		Control/Other diet	
Author, Year	HbA_{1c}. %	Weight. kg	HbA_{1c}. %	Weight. kg	HbA_{1c}. %	Weight. kg	HbA_{1c}. %	Weight. kg
Barakatun Nisak, 2013[r] [32]	7.51 (1.24)	66.8(11.5)	7.68 (1.13)	69.1 (13.3)	7.2 (0.2)	66.5 (1.6)	7.2 (0.1)	68.6 (1.9)
Parker, 2002[s] [47]	6.42 (0.83)	97.7 (17.4)	6.30 (0.77)	91.4 (18.2)	5.88 (0.78)	92.2 (16.8)	5.79 (0.59)	86.6 (16.8)
Walker 1995[t] [44]	6.8 (0.4)	80.1 (2.9)	6.4 (0.3)	79.5 (3.0)	6.6 (0.4)	78.8 (3.0)	6.5 (0.3)	78.8 (3.1)
Watson, 2016[u] [51]	8.0 (1.3)	97.3 (17.1)	8.1 (1.5)	101.5 (16.6)	6.7 (0.2)	88.4 (2.8, SEM)	6.6 (0.2)	93.8 (2.9, SEM)
Wolever, 2008[v] [45]	6.1 (0.9)	84.7 (2.6)	6.2 (0.9)	82.7 (2.5)	6.35 (0.35)	84.3 (0.2)	6.34 (0.35)	84.0 (0.2)

NR, not reported.
Data are mean (SD) where available or SE/SEM, where noted.
Where separate baseline values are not reported, the entire cohort values are used for both groups. Additional data received directly from authors: Dyson, 2007 [22], Larsen, 2011 [23], Jonasson, 2014 [24], Ben-Avraham, 2009 [25].
[a]Significant between-group difference. Figures in italic indicate SD/SE is for the change/difference.
[b]Patients with diabetes part of larger study cohort, not all data reported separately – obtained baseline values from author. Low-fat and Mediterranean diet study group data (means) combined.
[c]Outcome data include SD for the change/difference only, not the mean – used in meta-analysis.
[d]n = 14 Atkins Diet and 16 ADA at 1 year.
[e]No SE/SD available for weight – unable to include in meta-analysis. Recorded self-reported physical activity.
[f]CIs for the difference are reported. Self-reported physical activity.
[g]CIs available for change only.
[h]Figures in brackets are SEM. Did not report physical activity.
[i]Data for weight supplied by direct contact with authors. Did not report physical activity.
[j]CIs available.
[k]Figures in brackets are SEM. Recorded but did not report pedometer readings – stating no differences.
[l]Weight data are a sub-set of overweight patients only (n=69). SD only available for change. Did not record physical activity.
[m]Physical activity questionnaire used but not reported or discussed as part of analysis.
[n]Incorporated exercise as part of interventions and reported on this (no statistically significant difference between groups).
[o]Physical activity not reported.
[p]CIs only available. Physical activity recommended as part of intervention and measured using a validated survey but unsure if accounted for in analysis.
[q]Figures in brackets are SE. No mention of physical activity.
[r]Figures in brackets for post-intervention are SE. No mention of measurement of physical activity levels.
[s]Participants asked to maintain exercise levels, but not measured or reported.
[t]Figures in brackets are SE. Reports 'usual activity level maintained', but not reported.
[u]Figures in brackets post-intervention are SEM. Used treadmill speed as a marker of fitness and factored this into analysis.
[v]Figures in brackets are SEM. No mentioned of physical activity recording.

context of dietary changes, especially given the heterogeneity in the methods of dietary measurement employed, and their inherent inaccuracy.

Only 13 of the studies included in the present review demonstrated overall adherence to the prescribed quantity of carbohydrate, and in several cases where there was adherence, the quantity of carbohydrate consumed was very similar to the pre-study or baseline intake [43–46]. Although in each case there was a small reduction in carbohydrate intake in the intervention group, whether these studies achieved what they intended to achieve, and thus the validity of including them in this meta-analysis, could be questioned. The differences between the intervention and control diets often amounted to far more than a simple difference in the quantity of carbohydrate consumed. The nature of adjusting either the absolute amount or proportion of one nutrient automatically means either the proportion or absolute amount of other macronutrients will also be altered. In fact, this was sometimes the primary aim of the study [34,46,47]. The results of the present review are consistent with the findings from van Wyk *et al.* [9], who concluded that both low-carbohydrate and high-carbohydrate groups have difficulty in achieving and adhering to the prescribed level of carbohydrate intake, with a difference between groups as small as 8 g/day. Most trials used an intention-to-treat approach to the analysis, but in none of the studies included in the present review was additional analysis performed only in participants adhering to the protocol diet.

A wide range of methods of dietary assessment was used across the studies included in this review. Despite almost all the RCTs employing a dietitian to advise participants and administer the monitoring of dietary intake, there are inherent inaccuracies in whichever method is chosen, and comparison between methods has long been recognized as problematic [48,49]. If randomization had left significant differences between study arms with respect to the pre-study habitual dietary intake, this would have to be acknowledged as a potential risk of bias, but many of the included studies failed to measure or report the composition of participants' diets prior to the commencement of the trial [34, 36, 39, 41, 47, 50, 51].

Other limitations include the wide range of baseline HbA_{1c} values and adjustment of anti-hyperglycaemic medication. Participants with poorly controlled blood glucose were part of the exclusion criteria in several studies, but this may not be representative of a typical clinical population. Many studies used a protocol to adjust medication according to blood glucose during the trial, whilst others excluded patients based on their diabetes medication. Investigators either advised participants to undertake a recommended amount of physical activity each day or to continue with their usual activities, but the majority did not report or adjust for physical activity level in the analysis, which could be a significant limitation.

It is notoriously challenging to minimize bias in RCTs of dietary interventions, although numerous strategies have been recommended [52]. Blinding to treatment allocation of participants and those delivering the intervention is rarely possible, and the nature of dietary interventions involving complex lifestyle and behaviour changes means participants are likely to have a strong preference, which may, in turn, affect adherence and attrition. Participant bias and the Hawthorne effect are also likely in dietary intervention trials and may be evident in studies in the present review, such as in Jonasson *et al.* [24] in which participants were informed of the diet allocation prior to assessment of baseline nutritional intake. Most studies did not sufficiently report their efforts to minimize bias and could have described how blinding of outcome assessment and the personnel involved in data handling, for instance, might contribute to minimizing bias.

The present review provides an updated evaluation of research to establish the impact of carbohydrate restriction on glycaemic control in Type 2 diabetes and examines the potential impact of dietary adherence on the primary outcome, which previous reviews failed to fully address. Other systematic reviews and meta-analyses include database searches up to July 2017 [53] and did not include a recent study [54], which was included in the present review. Two reviews also looked specifically at low-carbohydrate vs low-fat diets rather than a range of control diets as in the present review [53,55], and the review by Sainsbury *et al.* [14] included studies with participants with Type 1 diabetes; therefore, the added value of the present review is the subgroup analysis of the 13 studies demonstrating relative adherence to the intervention diet. This aimed to address questions regarding the role of adherence in the primary outcome, however, may have been confounded by the proportion of studies in the moderate+ group which formed part of this subgroup.

The standardization of definitions relating to the level of carbohydrate intake is an important consideration. In the present review we categorized studies according to the proposed levels by Accurso [56] and Feinman *et al.* [28], which means some individual studies were re-categorized from their stated level of restriction to match these level descriptors. For example, studies often used ≤40% of total energy to define 'low carbohydrate', but this is now accepted as 'moderate carbohydrate'. The rationale for selecting this level of restriction is rarely explained, and it is likely that this merely represents an intake that is less than the habitual intake of western populations [57,58]; however, the restriction level is much higher than that likely to result in short-term improvements in glycaemic control, as demonstrated in the present review, and led to participants consuming levels of carbohydrate not dissimilar to their pre-study consumption.

The inclusion criteria for the present review were intended to encompass the breadth of evidence regarding levels of carbohydrate in Type 2 diabetes, but the large variation in

Table 4 Summary of recent meta-analyses

First author, Year	Number of studies	Participants, *n*	Range or level of carbohydrate restriction of included studies	Control diets used in studies	Outcomes* (restricted carbohydrate vs control diet)	
					HbA_{1c}	Weight
Ajala, 2013	8	810	20g to 45% energy	LF, LGI, MED, HC	Favours restricted CHO	No difference
Fan, 2016	10	1080	20g to 50% energy	LF, LGI, HC, CR	Favours restricted CHO	Favours restricted CHO
Huntriss, 2017	18	2204	<20g to 45% energy	unclear	Favours restricted CHO	No difference
Meng, 2017	9	743	5% energy to 130g	HC, ND	Favours restricted CHO	No difference
Snorgaard, 2017	10	1376	14% to 45% energy	LF, HC, HGI	No difference	No difference
Sainsbury, 2018	25	2412	<20g to 45% energy	LF, LGI, HC, MED, CR, ND	No difference	No difference
Schwingshackl, 2018	56	4937	<25% energy	LF	Favours restricted CHO	Not reported
Van Zuuren, 2018	17	2161	<40% energy	LF	No difference	No difference

CHO, carbohydrate; CR, calorie-restricted; HC, high-carbohydrate; HGI, high-glycaemic-index; LF, low-fat; LGI, low-glycaemic-index; MED, Mediterranean diet; ND, normal diet/healthy eating/dietary guidelines.
*Data for longest available time point.

the duration of included trials, the range of dietary approaches employed and whether included studies achieved the intended dietary changes may also limit the findings. Subgroup analysis suggests that including only studies lasting ≥12 months would not have any material impact on the overall pooled effect, a finding supported by other reviews that have grouped their analyses by study duration [14,59]. The exclusion of trials that did not report the carbohydrate intake of participants is recognized as a potential source of bias, however, this resulted in the exclusion of only one RCT [60] and most RCTs were excluded because of their duration or non-reporting of the primary outcome (HbA_{1c}).

The meta-analysis for HbA_{1c} includes a subgroup of trials of moderate carbohydrate in which a high level of heterogeneity is observed (I^2 83%; P<0.001). A wide range of different dietary approaches was employed in this group, which may have confounded the ability to draw conclusions from the pooled effect.

The present review did not undertake a meta-regression analysis to assess the effects of other variables on the primary outcome of HbA_{1c}, such as changes in diabetes medication, physical activity or weight. Many of the studies did not report on medication changes or physical activity, so these remain potential unobserved confounders. Weight loss is recognized as a significant predictor of improvements in glycaemic control in Type 2 diabetes and the network meta-analysis by Schwingschackl *et al.* [53] demonstrated a significant relationship between reduction in HbA_{1c} and mean differences in weight; however, meta-regression is not always appropriate where there are fewer than 10 studies in a subgroup [17], as was the case for two of the subgroups included in the present meta-analysis.

In conclusion, the present review provides evidence of short-term improvements in glycaemic control achieved by restriction of carbohydrate intake to 50–130 g per day; however, it suggests there is little evidence to support recommending a general restriction of carbohydrate intake for all people with Type 2 diabetes. Controversy in the area of dietary carbohydrate is likely to persist, with recent publications, such as the PURE study [61], calling for dietary guidelines to be reconsidered; however, data from studies of carbohydrate-restricted diets raise important questions about the long-term sustainability of such diets, given the poor overall concordance with the prescribed quantity of carbohydrate, even in a trial setting. As suggested by van Wyk *et al.* [9], it is likely there is significant variation in glycaemic response to carbohydrate among individuals, which may explain the inconclusive nature of trials. Future research should consider the acceptability of carbohydrate-restricted diets and how to identify people who will benefit most from being offered this approach. Researchers planning trials in this field should consider carefully the added value of further RCTs, given the number of systematic reviews already published. In order to add value, any future trials should be long-term (>12 months in duration), should adopt the prevailing definitions of low carbohydrate and should intend to keep both the caloric content of the diets in study arms and any changes in body weight equal. Current guidelines should reflect the short-term improvements in glycaemic control that diets restricted to 50–130 g/day carbohydrate can offer as the evidence-based approach in Type 2 diabetes.

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Supporting Information

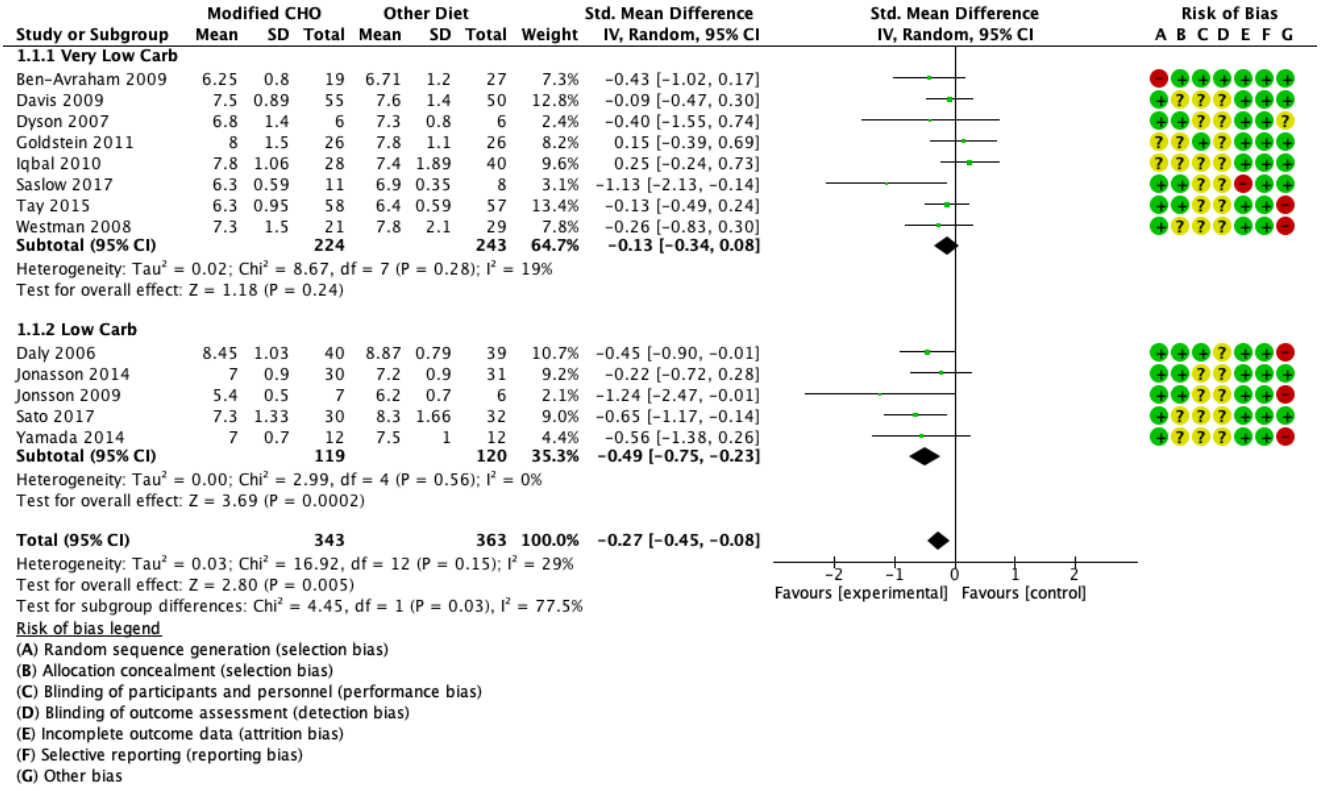
Additional supporting information may be found online in the Supporting Information section at the end of the article.

Figure S1. Forest plot for Body Weight.
Figure S2. Forest plot for HbA1c for studies reporting adherence to restricted carbohydrate diet**.**
Table S1 Results of individual studies: blood pressure and lipids.
Table S2 Carbohydrate: baseline vs prescribed vs actual and methods of dietary assessment.

2.1 Additional analysis by subgroup

Post-publication analysis was carried out to establish the significance of the definitions of low- and very low carbohydrate and whether grouping the two categories together would result in an overall pooled effect in favour of limiting carbohydrate below 130g per day, rather than differentiating between the very low and low categories. **Figure 3** presents the forest plot from this analysis.

Figure 3 – Forest plot for HbA1c combining low and very low carbohydrate sub groups



The analysis shows an overall effect when the sub groups are combined in favour of restricting carbohydrate to <130g per day [WMD -0.27% (95% CI 0.45, 0.08; *P* = <0.01); I^2 29%]. Whilst this is a clinically less significant reduction than seen in the low carbohydrate sub-group alone, it does suggest a simpler message can be conveyed for both health care professionals and patients who wish to pursue a carbohydrate restriction.

2.2 Implications for clinical practice & this thesis

This meta-analysis has provided further evidence for the short-term benefits of a low carbohydrate diet on glycaemic control in T2DM. Earlier research by the author,[3] the only study of its kind, indicates that this approach was not widely used by RDs in 2012 and there was disparity between specialist and non-specialist RDs in the likelihood of recommending a carbohydrate restriction, or the level of the restriction advised. This may have been related to professional training or confidence and highlights a lack of awareness of this as an evidence-based approach, which has been included in the nutrition guidelines since 2011. The lack of evidence for one universal level of carbohydrate intake for all people with T2DM, together with the variations in practice outlined in earlier research, strengthen the need for this thesis to develop a framework in which carbohydrate advice by RDs can be improved.

2.3 Supplementary material for Chapter Two

Supplementary material listed in this paper can be found in the appendices (please see page 184 for a list of appendices and corresponding page numbers).

CHAPTER THREE

QUALITATIVE METHODOLOGY & METHODS

3.1 Introduction

This Chapter will describe the qualitative methodology, the rationale for the methods chosen as well as a detailed account of the research undertaken. As outlined in **Chapter One**, the aim of this thesis was to inform the development of an intervention framework to advise patients with T2DM about carbohydrate. This is in the context of conflicting evidence, specifically relating to the optimal quantity of carbohydrate in T2DM as demonstrated in **Chapter Two:** Systematic Review. To achieve this, the research undertaken for this thesis intended to understand the way in which carbohydrate advice is both experienced by people with T2DM and given by registered dietitians.

Qualitative research allows investigators to explore participants' understanding of a topic in the context of their own lived experience, which can provide a rich background from which to draw meaning and explanation.[82] This makes a qualitative approach ideally suited to answering the research questions of this thesis. The justification for the methods chosen will be further developed later in this chapter. There is evidence of the impact of involving patients or service users in designing interventions,[83,84] guidelines [85] and in improving the quality of care.[86] Therefore, in developing the research proposal, it was felt that the views of patients *and* professionals would be vital in developing an intervention which would be useful, meaningful and acceptable to both parties. This led to a sequential qualitative study design and collection of data from both patients with T2DM and RDs.

The inclusion of a Stakeholder Group (SG) consisting of patients, professionals and members of the public was central to the methodological and philosophical basis of the study, which will be discussed later in this Chapter. This approach was intended to achieve more than merely 'Patient and Public Involvement' (PPI), as it was hoped that the participation of SG members in the running of the research would result in an intervention that has greater credibility within the communities in which it will be used. PPI can also help researchers avoid or overcome practical hurdles, such as barriers to recruitment, or highlight areas worth investigation not previously considered by researchers.[87]

3.2 Research Design & Over-arching Theoretical Framework

Chapter One (Section 1.10, page 19) outlines the use of the MRC guidance [80] on the development of complex interventions to inform this research. This research did not intend to fully model the process and outcomes that would be necessary in a full-scale clinical trial. However, it was concerned with informing the development of an intervention that would be sufficiently well-defined and described, and in an acceptable form for professionals and patients alike, that could then go forward and be used in a feasibility study and subsequently a full-scale clinical trial.

The methods of data collection used were semi-structured interviews [88] with patients with T2DM and focus groups with RDs.[89] A study protocol was prepared as part of good clinical practice and for submission to ethics.

3.3 Ethical Considerations & Consent

This study involved both NHS staff and patients. Although some patient participants could have been recruited via Diabetes UK voluntary groups as members of the public, the expectation was most would be recruited through contact with their NHS Dietitian or other diabetes professional, therefore it was necessary to request an ethical review and approval from an NHS REC. NHS Research Permissions were also requested once the NHS REC application is underway. The Integrated Research Application System (IRAS) was used to request ethical review from the NHS REC and a favourable review was obtained after making some minor changes requested by the REC (REC Reference 16/YH/0192, favourable opinion received 10/05/2016, & HRA Approval, Appendix 5). Approval was also sought and obtained from the University of Birmingham.

So that informed consent to take part could be given, once patient participants had been given an opportunity to read the information given to them about the study (at least 48 hours), the researcher discussed the study with them, answered any questions and checked understanding before gaining their consent. The same process took place for the dietitian participants, and the author was the sole point of contact for any queries.

The latest guidance from the Health Research Authority [90] was used to inform all aspects of the study from an ethics perspective, particularly regarding consent and participant information.

3.4 Philosophical Worldview

All research is underpinned by a philosophical worldview and therefore as a prelude to the justification of the research methods for this thesis, it is worthwhile to explore the philosophical worldview of the researcher, since certain assumptions are made regarding the ontology ('what is there') and epistemology ('what is known and how is it known') within the choice of research methods,[91] despite authors often failing to acknowledge this.[92] In order to make knowledge claims the researcher has a duty to illuminate the epistemological basis on which the research has been carried out.

Ontology in the philosophy of research is concerned with what exists and what is real [93] and can be described on a spectrum ranging from naïve realism, in which objects or phenomena are observed as they really are, independent from the observer and are perceived correctly through the senses, through to relativism in which it is believed that there is a 'socially constructed reality',[94] dependent on the context and vantage point.

Epistemology is the theory of knowledge, of how we acquire our knowledge of the external world and the extent to which there can be certainty of this knowledge.[93] Epistemology may also be described on a spectrum from positivism to interpretivism, with the positivist paradigm being epitomised by the Randomised Controlled Trial (RCT), where causality is tested without necessarily examining the underlying cause or mechanism (empiricism).[95] This epistemological standpoint has traditionally viewed the researcher as value-neutral; however, it is unlikely that this is either possible or entirely necessary for the production of reliable and valid research findings, provided researchers account for the potential influence of personal bias.[96] It is rarely possible for any method or researcher to be entirely free from

bias, but the reflexive researcher utilising qualitative methodology will acknowledge the potential for their own bias as part of the analysis of findings.[96] An interpretivist epistemology [93] holds that knowledge is socially constructed and highly contextual, and therefore is often the epistemology underpinning qualitative research methods.

The philosophical standpoint adopted by the author and therefore underlying the methods chosen for this research is Critical Realism. Bhaskar is a key figure in Critical Realism,[97] which adopts a realist ontology together with a constructivist epistemology, meaning that critical realists believe there is a reality that is stratified at different levels (empirical, actual and real) and knowable even if not all of it is observable, and which may exert effects on causal mechanisms that are context-dependent. This can lead to there being multiple versions of reality, as constructed through different contexts and interpretations, and that meaning can be attributed to the outcome or the observed effects by understanding the deeper (real) levels of the ontological strata to find generative mechanisms. For this author, as a novice researcher, this means that there are a number of levels at which phenomena can be observed and understood, including the underlying causes, but this observation and understanding is highly dependent on the context. It therefore holds that this worldview can be applicable to understanding the same experience (advice from an RD to a person with T2DM) from different perspectives and in different contexts, and therefore may be used to justify the choice of methods.

3.5 Justification of Qualitative Research Methods

Qualitative research encompasses a broad range of methods and methodologies that are concerned with describing, understanding or explaining phenomena, in contrast to

quantitative methods which attempt to answer research questions through the use of frequencies or numerical measurements of effects.[98] Another distinction relates to generalisability, where the aim of quantitative research is to be representative of, and generalizable to, a much larger population.[99] This is not typically the goal in qualitative research, which is firmly embedded within social and cultural contexts, but that does not mean qualitative research is incapable of producing 'cross-contextual generalities'.[82] In other words, findings from qualitative research may be applicable across different contexts and not solely restricted to the context in which they were generated. Rather than generalisabiilty and the external validity that is sought in quantitative research, qualitative research seeks to produce findings that are considered reliable and trustworthy,[100] and this is achieved via a thorough description of the conduct of the research and the context and theoretical frameworks within which it was undertaken. Whilst not formally undertaken for this thesis, attention was paid to the accepted standards in reporting qualitative research: 'COREQ' (Consolidated criteria for Reporting Qualitative research).[101]

A greater understanding of the views, practices and preferences of people with T2DM will inform the development of a framework for 'Carbohydrate Awareness Advice'. This could have been achieved through quantitative survey-based research, however, eating and food choice are situated within a highly complex social and cultural context [36] as outlined in **Chapter One** (section 1.1, page 5) and to attempt to develop a meaningful dietary intervention without acknowledging this context would be an oversight. In relation to advice targeted at self-management in long term conditions, in a paper examining the rise of qualitative research methods in studying chronic disease, Conrad [102] concluded there is a need to "increase our sociological understanding of illness as a lived experience" and Furler

et al [103] noted self-management interventions tend to focus on education and advice-giving rather than the psycho-emotional issues of patients.

3.6 Rationale for the use of Mixed Methods Research (MMR)

The proportion of health research classified as MMR has been increasing for a number of years and England has seen the level increase to 18%.[104] The reasons for the increase in popularity of MMR has not been extensively researched and it could be due to a number of factors, including a greater awareness of MMR methods, increasing popularity of pragmatist and constructivist epistemologies linked to MMR, or a rise in the popularity of qualitative research in what has been a traditionally very quantitative field.[105] The key difference between quantitative and qualitative research is the ability for quantitative research to provide a numerical or statistical answer to a research question or hypothesis, and for qualitative research to explore meaning, mechanisms, views or experiences. In MMR, the combining of these two approaches is not merely adjoining them but is concerned with creating that which is greater than the sum of its parts. In other words, the benefits of MMR should equal more than the separate value of the qualitative and quantitative parts. In the case of this thesis it was necessary to establish the evidence base for the amount of carbohydrate recommended in T2DM through the use of a meta-analysis. The sequential mixed methods design allowed for the integration of the quantitative findings throughout the qualitative and framework development.

3.7 Rationale for use of theory in research

Qualitative research is often characterised by its inductive, iterative approach to the analysis of data and the use of thematic analysis has become a common approach in qualitative

research.[106] This approach draws explanation and meanings and develops theories directly from the data as a well-established research method. However, the application of a theoretical model to the data can allow for additional perspectives or meaning to be derived and can contribute a structure to the analysis that is helpful in elucidating the findings. Researchers have found the use of a theoretical model to show additional meaning and detail in a way their initial thematic analysis did not.[107] Criticism of the use of theoretical frameworks in qualitative analysis centres around their pre-determined application to a data set that might in itself limit how data are collected, coded or analysed, however Braun & Clarke [106] suggest thematic analysis alone 'has limited interpretive power beyond mere description if it is not used within an existing theoretical framework…'.

3.8 Rationale for Choice of Methodological Approach

This research employs a 'theoretically flexible' [108] approach that is not attached to a particular framework. Methodological approaches exist that include a theoretical framework and where the method and its philosophical underpinnings are intrinsically connected. Two such methods are Grounded Theory (GT) [109] and Interpretive Phenomenological Analysis (IPA),[110] both of which will be briefly described below, followed by a rationale outlining why they were considered unsuitable for use in this research.

GT was established in 1967 by Glaser & Strauss [111] and its core principle is that the researcher should approach the work with no *a priori* ideas or theories about the data that might be obtained. Theories are developed from a constant comparative method of reviewing and reflecting on the data, meaning they can be continually amended as new data is collected.

IPA comes from a set of approaches termed hermeneutics and originates from its use in psychological qualitative research. It is particularly concerned with attributing meaning to the lived experiences of individuals, interpreting how they make sense of their experiences, typically uses interview data and is often based on small sample sizes.[112]

Whilst these methodologies encompass both the **method** of analysis *and* the underlying theory, Thematic Analysis (TA) [106] is described as a method which can be underpinned by a number of different theoretical approaches. This makes it well suited to addressing many of the same research questions that would be answered by more established approaches. In this thesis, TA [106] was intended for use from an interpretivist stance, meaning that it was not only a method for describing the face value of the data obtained and was more than simply a means of organizing the information presented in the findings. TA was selected as the most appropriate approach when compared to GT or IPA due to differences in their methods which were deemed incompatible. In GT, the concept of 'bracketing' and approaching the data collection with no *a priori* ideas regarding what might be found was incompatible with the researcher also being an RD and having had many years of experience working with people with T2DM.

Furthermore, there has been a divergence of types of GT [111] and as such, navigating the multiple types of GT methodologies [113] was felt to be unnecessarily complex. As briefly mentioned above, the concept of a complete lack of *a priori* theory in classical GT was unrealistic and not easily reconciled with the researcher's position as an 'insider'.[114] The 'bracketing' of the researcher's experiences as an 'insider', given the field and topic in question, would be particularly challenging, making both GT and IPA inappropriate.

Despite the many similarities between IPA and TA, the key differences in the approaches to the coding and analysis of data are also problematic. Coding in TA is across all the data items, after a period of familiarisation with the entire data set,[106] whereas in IPA the coding and theme development is done for each data item in turn.[115] It was felt that coding across the data set, before developing initial themes, would best suit the research questions and the different types of data (patient interviews, focus groups with dietitians) used in this research.

3.9 Justification for Interviews with Patients & Focus Groups with Dietitians

Interviews, whether individual or group, are one of several ways to collect qualitative data to answer research questions.[82] The decision to conduct either group or individual interviews is based on a number of factors, including the nature of phenomena to be studied, the study population and the research aims.[116]

The exploratory nature of qualitative research makes it particularly suitable for researching topics about which little is known, and the individual research interview is recognised as one of the most common methods of data collection.[117] Research interviews can range in the degree of structure from in-depth through to structured, and the semi-structured interview allows the researcher to direct the topics to be covered.[117] It was chosen for interviewing patients in this study partly for this reason but also due to the potential for confidential information about individuals' health to be shared during the interview. Although some have suggested that focus groups are more likely to lead to more personal or sensitive disclosures,[118] issues regarding willingness to participate and gaining sufficient depth of contribution from each participant remained concerns for conducting focus groups in this population, and therefore individual interviews were chosen.

Focus groups are 'perceived as a method which can generate complex information at low cost with the minimum amount of time' [119] and are increasingly used as a data collection method in health research.[120] The critical realist philosophy on which this research is based is central to defining the meaning and function of the focus groups within this research.[121,122] Key features of focus groups relevant to this research are the active role of participants; the ability to generate contextually meaningful understanding about a topic on which there is currently no consensus (carbohydrate awareness advice); and the concurrent use of data from other parts of the study (the earlier Systematic Review, the qualitative interviews with patients). The critical realist tenet that there exists an external reality but that our knowledge is socially constructed is entirely compatible with this use of focus groups.[123] It was considered there is significant value in facilitating a group of professionals to convene and debate this topic and that this process of co-construction of data in qualitative methods was suited to the research questions. It was felt the dynamic interaction between participants may assist with the formation and clarification of RDs' own views on the subject. Focus groups are said to encourage participants to 'comment, explain, disagree, and share their views',[124] making them perfectly suited to helping to answer the research questions of this thesis. Furthermore, as an 'insider' researcher, there would be challenges in overcoming bias and pre-conceived ideas about dietetic practice if observations had been chosen as a method to replace the first round of focus groups. It is for these reasons that observation of dietitians in clinical practice was not carried out in place of the focus group approach and, although non-participant observation is a valuable tool in research, this is more commonly used in ethnographic research.[125]

3.10 Development of the research question

The research question was developed following earlier work which examined the practice of RDs in advising patients with T2DM about carbohydrate,[3] as well as another study looking at patients' understanding of the topic.[126] Other work, such as the James Lind Alliance Research Priorities Setting Partnership [127,128] has also highlighted the importance of questions regarding nutrition, and specifically carbohydrate, to both patients with T2DM and health professionals. Nutrition-related questions featured three times in the Top 10 research priorities, which are considered the most important unanswered research questions.[129]

The Systematic Review and Meta-Analysis reported in Chapter Two concluded that there is no overall effect of restricting carbohydrate on HbA1c or body weight, however subgroup analysis found that restricting to less than 130g per day does have a significant clinical effect on HbA1c and body weight. The lack of an overall effect, and the absence of clear effects below 50g, is probably due to a high degree or inter-individual variability in response, as suggested by an earlier paper.[130] This supports the continuation of the research in answering the remaining research questions.

3.11 Part One – Patient Interviews

3.11.1 Sample & Setting

Patient interview participants were eligible to take part if they met the following inclusion criteria:

- Adult of 16 years and over (no maximum).
- Previously received dietary advice from a Registered Dietitian in a one-to-one setting within the last 24 months (confirmed by checking their NHS record).

- English spoken or understood or prepared to be interviewed with a professional interpreter.
- Prepared and willing to take part in an in-depth research interview of up to 60 minutes.

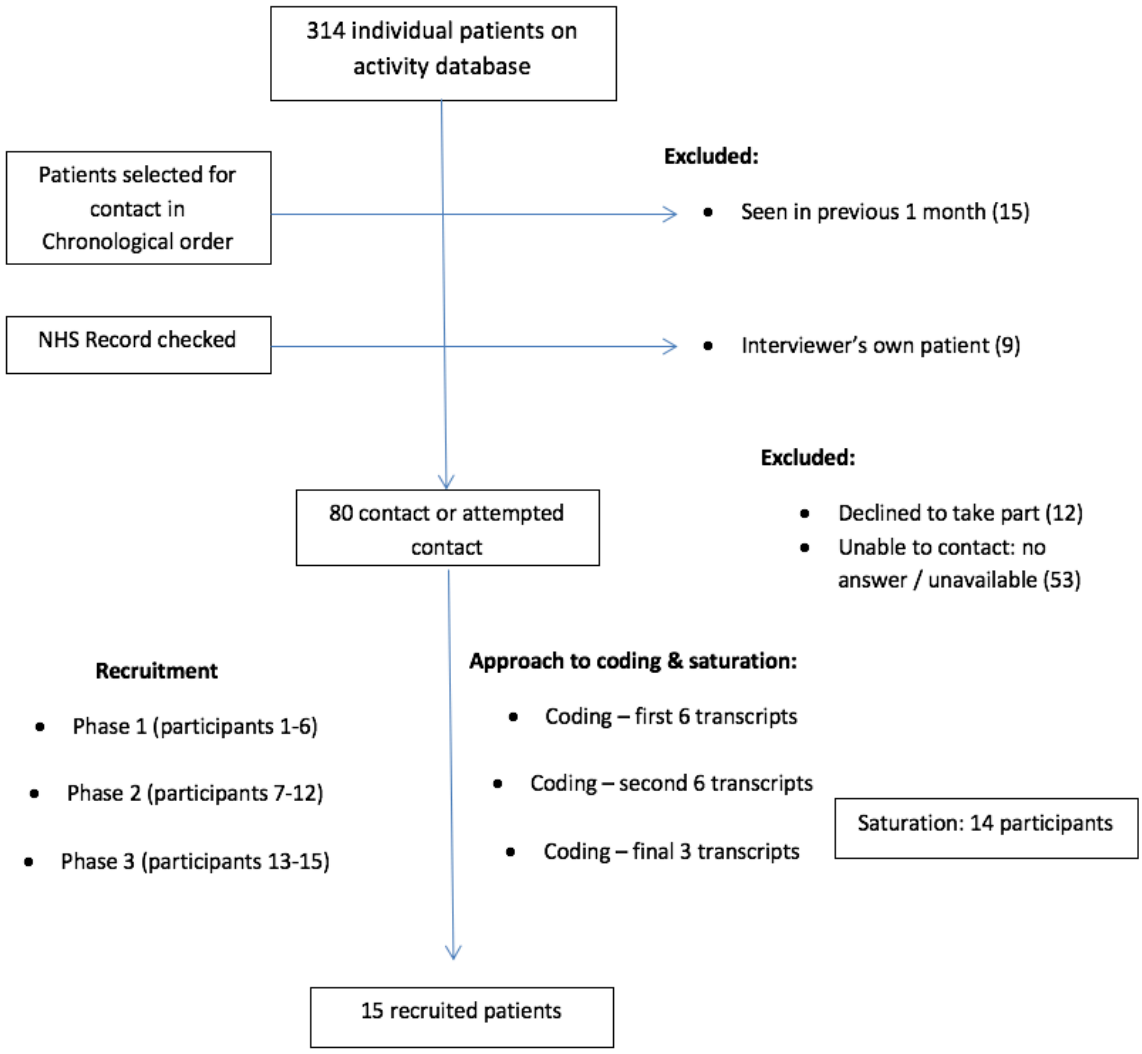
Patient participants were excluded if there was uncertainty over their diagnosis, if the advice was received during pregnancy or if other diabetes complications were present that might require specific nutritional advice.

Purposive sampling [131] was used to select patients for semi-structured interviews. The sample was drawn from patients seen by Birmingham Community Nutrition (BCN) Dietitians over the period from April 2015 to October 2016. BCN provides outpatient dietetic care in a wide range of community clinics across the diverse metropolitan area.[132] Patients are typically referred by their GP and may be seen as part of a joint specialist clinical service together with a diabetes specialist nurse, or in a dietitian-led clinic. Appointments are usually offered over a 3-6 month period, sometimes longer, and are 15-45 minutes in duration.

A dual approach was adopted for recruitment of participants. Despite access to an activity database of patients seen in BCN and from which it is possible to confirm who has seen an RD, because it is not the only dietetic service in Birmingham providing one to one advice to people with T2DM, advertising to members of the public was also used, in an effort to minimize bias. However, advertising through staff newsletters in the local NHS Trust, to members of the local Diabetes UK (charity) support groups and via the personal networks of the Stakeholder Group members yielded no participants that met the inclusion criteria.

Although four potential participants came forward through these routes, in each case they did not meet the requirement to have received advice from an RD in a one to one setting in the previous 2 years, based on self-reporting. The database from which the sample was drawn is a patient administration system that records activity (patient contacts) and links to a clinical records system that captures the clinical information within Birmingham Community Nutrition. These records are coded according to the type of activity or intervention, and this allowed searching and reporting in order to generate the list from which recruitment was carried out. A search for contacts coded against 'dietary advice for diabetes' from April 2015 to October 2016 found 1500 recorded contacts with 314 individual patients. **Figure 4** outlines the process of recruitment.

Figure 4 – Recruitment & Saturation Flow Diagram



Unlike in quantitative research, it is rarely possible to specify in advance the precise number of participants required to achieve the objectives of a qualitative study. The required sample size depends on the depth and nature of both the interviews and the analysis. There are no agreed guidelines, with suggested numbers ranging from 5 to 60.[82,133] A common approach is to continue until data saturation occurs;[134] in other words, until no new data is being

collected. Although it is impossible to predict the point at which saturation will occur in advance, research has suggested that 'higher level' thematic saturation could be expected within 12 interviews,[135] meaning that no new themes were developed after this point, even if 100% of codes had not yet been provided. Other research has found saturation has been reached at between 12 interviews [134,136] and 17 interviews,[137] whilst some have differentiated between saturation of codes and saturation of meaning, finding that codes were saturated at 9 interviews and meaning at 16 interviews.[138] Given the focused nature of the topic in this research study and the likelihood that participants have had similar experiences in receiving advice from an RD, it was anticipated that theoretical saturation may be reached with between 12 and 17 patient interviews.

In identifying potential participants from the database, the only information available was the patient identifier (a local reference number and the NHS number), the date of the contact and the name of the dietitian. Patients who had received advice from the interviewer were not contacted to take part in the study to minimise the risk of bias. To check eligibility the patient's electronic clinical record was accessed to confirm patients had seen a dietitian in a one to one consultation in the previous 2 years, and to obtain their contact details. Confirmation of whether the patient had any one to one consultations with an RD was not based on self-report but on the clinical records. On reviewing the information within the database, it was decided that patients seen for the first time in the last month would not be contacted and so each patient seen from one month onwards was reviewed for eligibility and contacted for recruitment in chronological order. This exclusion was based on the presumption that patients seen once and receiving dietetic treatment for less than one month may not have had time to reflect fully on their experience of seeing an RD.

Figure 6 describes the process involved in the recruitment of participants from the database. At the end of the patient interviews, a total of 15 people with T2DM had been recruited and interviewed. Patients were recruited for interview from a population total of 314 individual patients, of which contact or attempted contact was made with 80 patients. There were 12 patients who declined to participate and 9 further patients who could not be recruited as they had received their dietetic care from the researcher who would conduct the interview (Figure 4). As already outlined, this was deemed inappropriate due to the nature of the interview in exploring the patients' experience of their dietetic care.

3.11.2 Recruitment – Patient Participants

Potential patient participants were initially contacted by telephone to explain the purpose of the research, to confirm they met the eligibility criteria and to determine if they were interested in taking part. Interested patients were then mailed the participant information and consent (Appendix 6) and a convenient time was arranged to conduct the interview. Potential participants were not informed of the dual role of the researcher (as interviewer and an RD) to minimize the risk of role confusion and blurring of boundaries, as some research participants may feel obligated to take part if they are aware they are being interviewed by a health care professional.[139] There is also the risk that some patients may confuse research interviews with a therapeutic encounter, resulting in over-participation,[140] which may affect the quality of the data obtained and leave the participant feeling dissatisfied with the experience, or potentially exploited. Avoidance of this confusion is what framed the way in which the purpose of the interviews and the role of the interviewer were explained at recruitment.

3.11.3 Semi-Structured Interview Schedule

A structured interview topic guide [141] was developed for the patient interviews (Appendix 7) and was used to guide the interview questions although follow-up questions and additional questions were asked depending on participants' responses. The schedule was developed by the interviewer based on the research questions and aims of the study. Research supervisors also reviewed the schedule and it was subject to ethical review by the Health Research Authority (HRA) together with all other study documentation. Ethical review did not result in changes to the interview topic guide. Although the schedule was not piloted, it did not change significantly throughout the course of conducting the interviews and supported a framework on which to base the interviews without over-restricting the types of questions and discussion that followed.

3.11.4 Justification for the use of scenarios in patient interviews

As part of the interview a scenario (Appendix 8) was used in order to elicit responses from participants regarding food choices in a non-threatening way. This was chosen because revealing information about food choices and dietary patterns can be a personal and potentially intrusive subject, as indicated by reluctance to report food intake [142]. Furthermore, interviewees are liable to give answers to questions which they think will please the interviewer, to answer 'correctly' or in an attempt portray themselves in a positive light.[143] The use of vignettes or scenarios can help overcome some of this bias inherent in qualitative interviews and can help to provide a focus and to further explore participants' responses.[144] This method of asking participants to imagine how they might make theoretical food choices in an impersonal and impromptu manner, may avoid the tendency to give what they perceive to be the 'correct' answer. It also avoids the risk of feeling judged by being

asked to explain past food choices, or giving responses which patients feel they should give, often referred to in the literature as social desirability.[145] The ultimate aim of the food choice scenario or vignette was to explore and understand more deeply the factors affecting decisions regarding food choice and to establish what, if any, influence their contact with the dietitian had on those decisions, in a non-threatening way.[146] Initially the scenario was described to the participants by the interviewer and a list of foods from which to choose was read aloud, however after the first interview it was clear that the interviewee had difficulty recalling and selecting from the verbal list of foods. For all subsequent interviews the list of foods was replaced by photographs of exactly the same foods, from which point the participants found it much easier to consider and select their choice.

3.11.5 Semi-Structured Interview Data Collection

Options for the location of interviews included the patients' own homes, a local health clinic or office space in an NHS site or University campus. Twelve of the interviews were conducted in the patients' own home and the choice of location and time for the interview was led by the patient. Of the 3 patients who chose not to be interviewed in their own home, two were interviewed in a local health clinic and one in NHS office space on a hospital site. This patient-led choice was important to minimize the potential for power imbalance between the researcher and the participant, although it is suggested there is no 'ideal' location for a research interview as all settings have both advantages and disadvantages, depending on the context of the interview.[147] There is typically a pragmatic element to the choice of location, given that the convenience of taking part may determine potential participants' willingness to consent.

Interviews were allocated 60 minutes; however, the average duration was much less than this at just over 24 minutes (range 16-37 minutes). Interviews were recorded using a digital voice recorder [Philips DVT800] and were subsequently transcribed verbatim by a professional transcription company. At the time of the interviews, data was also collected regarding the participants' diabetes management using the Case Report Form (CRF) as per the study protocol (Appendix 9). These details included duration of diabetes, number of contacts with a dietitian in the previous 24 months, type of diabetes treatment and degree of blood glucose control (HbA1c). Where participants were unsure of some of the information requested, permission was sought by the interviewer to retrieve this data from the participants' health records, which was done immediately after the interviews. This information was then used to assist in interpretation of the interview data.

3.11.6 Analysis of patient interview data

3.11.7 Analytical Framework

As discussed in section 3.8 (page 34), Thematic Analysis [106] was chosen as the method of analysis of the interview data.

3.11.8 Coding of transcripts

Transcripts were first checked and cleaned against the digital recording to confirm they represented an accurate record of the interview. Cleaning the transcripts involved completing gaps where transcribers were unable to decipher what was said or where voices overlapped, and correcting misspellings of technical terms.

The process of familiarisation is an important aspect of Thematic Analysis,[106] and so transcripts were read and re-read to become familiar with the content before any coding could take place. The process of coding involved marking words or sections of text according to their significance and potential meaning, which could be either latent or semantic depending on what was identified. The majority of codes used were semantic, since the principal aims of this research are concerned with describing, and codes were either single words or phrases. The inductive approach used to code the data and which led to the formation of overarching themes, was based principally on 'articulated data', [148] which means that it relates closely to the questions posed as part of the interviews. It was not intentional to code the data according to the questions asked during the interviews. Management of the data, including coding of the texts was undertaken using NVivo 11 [149] and was an iterative process where previous codes and transcripts already coded were revisited to check for co-significance and to revise codes accordingly. Transcripts were coded individually, but in batches of 5-6, on receipt of the transcribed recordings from the transcription company. After coding each batch of interview data available, codes were grouped according to their collective meaning or significance, which then led to the development of themes. The process of coding and theme development in batches allows the researcher to identify when saturation of the data has occurred.[133] In this research study, saturation was determined at the level of themes, rather than at the level of individual codes, meaning saturation was reached when the codes attributed to the data in new data items did not lead to the development of any new themes. Thematic saturation was reached after 14 patient interviews (Figure 4). The themes were developed at an overall level, in line with the batches of interview transcripts, rather than on a per patient basis. Research supervisors

independently reviewed a selection of interview transcripts and met to develop the codes and to discuss and agree emerging themes.

3.11.9 Application of a theoretical model

Chapter Five applies Kleinman's Explanatory Model to the thematic analysis of the results presented in **Chapter Four**. Kleinman's model was discussed briefly in **Chapter One** (section 1.1 page 5 & section 1.9 page 20), however a full description of the methodology used and the rational for selection of the model are provided in **Chapter Five**. The rationale for the use of a theoretical model is to facilitate the exploration of a deeper understanding of the experiences described in **Chapter Four** [150] and is discussed in sections 3.7 & 3.8 (pages 29 – 32). This applies equally to the patient and FG methodology described in the following section.

3.11.10 The Reflexive Researcher – Patient Interviews

The researcher has practiced as a clinician in this field for over 16 years and has professional experience of the gap in the evidence base which has led to the development of this research question. As an RD with many years of experience working with people with T2DM, and with a strong professional interest in behaviour change and person-centred approaches, it is important to recognise the personal standpoint and approach taken in supporting people with T2DM and the potential influence this may have on the research.[140] There are potential advantages in having significant experience in counselling people with T2DM about their diet, for example the advanced communication skills and consultation skills developed over many years. However, this experience could also create an unconscious bias regarding the nature of T2DM and the ways in which people with T2DM talk about their past experiences with RDs,

not least because these experiences are likely to be with colleagues known professionally to the author. Such influences are typically mitigated, at least partially, by the use of reflexivity.[151,152] The author would describe himself as professionally open-minded with a good degree of skepticism. As described in section 3.11.2 (page 39), it was decided that the researcher would not reveal to patient interview participants prior to the completion of the interview, unless asked directly, their role as an RD. It was felt that this would unduly influence the responses of the participants and would alter the context of the interview, thereby adversely affecting the data obtained.

3.12 Part Two – Dietitian Focus Groups

3.12.1 Sample

Inclusion criteria for RD participants included those who were:

- UK Registered Dietitians (registered with the Health & Care Professions Council).
- Providing one to one advice for patients with T2DM.
- Prepared and willing to take part in two rounds of focus groups, each lasting 60-90 minutes.

RD participants were excluded if they had fewer than 6 months' post-registration experience as this is considered a period of preceptorship where newly qualified professionals are supported to develop confidence and enhance competence.[153] Dietitians were also excluded if they were not advising patients about food choices in T2DM, e.g. patients who receive all their nutrition via a feeding tube, or patients with T2DM seeing the dietitian for reasons completely unrelated to diabetes.

3.12.2 Recruitment – Dietitian Participants

A total of 34 dietitian participants were initially recruited through a wide variety of means throughout the UK:

Table 5 – Recruitment sources for dietitian participants

Recruitment route	**Number (%)**
Twitter and other social media	3 (8.8)
Response to advertisement in *Dietetics Today*	2 (5.9)
Personal contacts (email)	7 (20.5)
Network contacts (email)	22 (64.7)
TOTAL	34

Most Focus Group participants were recruited through network contacts, using regional, national and local groups to circulate recruitment emails. An incentive for participation was offered in the form of high street shopping vouchers, to the value of £25 per participant, per group attendance. Although research shows mixed results regarding the impact of financial incentives of this nature on levels of participation in studies,[154–156] the use of an incentive was felt to be important because dietitian participants were committing to take part during the evening, outside of their normal working hours, at a central location in their town or city. This was approved as part of the ethical review process.

It is suggested that the ideal number of participants for a focus group is between 6 and 12 [157] therefore, based on existing research, it was decided the optimal number of participants to include in each group would be 8.[134,157,158] The target (or maximum) number of dietitian participants was 32 (4 locations x 8 participants), however there was some intentional over-

recruitment to allow for drop-outs and late cancellations. The rationale for the number of groups and their repetition is outlined in the sections which follow.

Applying the concept of saturation to sampling for focus groups is challenging because whilst the assessment of saturation takes place in the analysis stage after data collection, decisions about recruitment have to be made in advance.[159] Unlike patient interviews where more participants can be relatively easily recruited and interviewed if necessary, FGs involving health professionals in a range of locations across the country require a greater degree of operational advance planning. Research has indicated that most themes in data derived from FGs will be identified with just three FGs.[160] It is on this basis that the number of groups was chosen and, rather than traditional saturation, the consistency of themes across groups will be examined in the analysis of the FG data.

A total of 24 dietitians participated in the focus groups due to several participants in some locations withdrawing before the group took place. All of those who withdrew gave similar reasons citing their unavailability due to work or other commitments, and in a couple of cases it was due to illness. None of the participants who withdrew indicated they had changed their mind about participating. Three of the focus groups included 6-8 participants each, with just one which included 3 dietitians. This group would have been cancelled if the facilitator had known in advance of the poor attendance, however 6 people were expected up until the day of the group. The characteristics of the sample are given in **Chapter Four**, however it was decided not to give individual-level socio-demographic or other details, due to the ease with which individuals could potentially be identified by those working in the field.

3.12.3 Settings

Focus groups were held in four locations across the United Kingdom between January and February 2017:

- Birmingham
- London
- Cardiff
- Glasgow

Due to the potential for regional variations in practice, as has been documented in other areas of healthcare,[161] it was felt that there was merit in undertaking focus groups in multiple locations to include the countries of England, Scotland and Wales. Although uncovering regional variations was not the aim of this research, analysis of the findings related the themes developed to which groups contributed data. The Birmingham and Cardiff groups were held in a meeting room at a city centre hotel, the Glasgow group was held in a University building and the London group in a meeting room at an NHS Health Centre. All focus groups took place mid-week (Wednesday or Thursday), were early evening (approximately 18:00) to allow participants to attend immediately after work, and refreshments were provided for participants.

3.12.4 Focus Groups Data Collection

A topic guide (Appendix 10) was used to guide the facilitator and to ensure some consistency between groups. There were 9 standard questions for the first round of FGs, including those that related to the patient case studies presented as part of the group, and the main topic areas related to the dietitians' priorities for advice, the types of carbohydrate advice they give

and how they determine which patients receive which types of advice. The second round of FGs had a separate topic guide (Appendix 11), however these groups were focused on one central question "How should we advise patients with T2DM about carbohydrate?" and subsequent questions related to clarifying how RDs felt advice could be improve and what should be included.

FGs were recorded using a digital voice recorder [Philips DVT800] and were subsequently transcribed verbatim by a professional transcription company. Data was also collected regarding the participants' experience and role (e.g. specialist or non-specialist) using a CRF at the time of the group. This was used to assist in interpretation of the data. FGs were all facilitated by the same researcher and lasted 55 minutes on average, however the duration of the first round of FGs was on average longer than the second round (63 minutes vs. 48 minutes).

3.12.5 Use of Patient Case Study 'vignettes'

Three patient case studies or scenarios were developed for use as part of the FGs (Appendix 12). These were used to elicit responses about views or professional practice in relation to certain types of patient or treatment regimens, which may be commonly used in T2DM. The rationale for use of such vignettes is supported by literature which suggests that they may limit potential 'Hawthorne' effects [162] where research participants may behave differently simply because they are being observed as part of a research study. Furthermore, the case studies show a good level of reliability in relation to real-world clinical practice or decision-making [163]. For the facilitator, they served as an opportunity to confirm or refute differences

in the RDs' reasoning for answers to earlier questions, thus adding further reliability to the data obtained.

3.12.6 Two Rounds of FGs

FGs were conducted in two rounds, meaning that each participant attended FGs 1 and 2 in their respective locations. The paired sets of groups were separated in time by approximately one calendar month. The purpose of running the groups in this way was two-fold; firstly, to minimize the time commitment required from each participant at the end of the working day by avoiding a group lasting 120 minutes or more, and secondly to separate the two aims and to allow the sharing of other study information between focus groups. This is demonstrated in **Figure 5**, which describes the study flow and shows how the different elements (systematic review, patient interviews, focus groups & stakeholder group) were all intended to interact. There was a risk that some participants would not attend the second round of FGs, however attendance was similar across both rounds of FGs.

The principal aim of the first round of groups was to establish dietitians' views of their current practice with respect to carbohydrate advice for people with T2DM. For the second round, the aim was to understand how dietitians thought the current approach could be improved and how we should be advising patients about carbohydrate in T2DM.

Following the first round of groups it became clear that the knowledge of current guidelines was not equal amongst the dietitians in some of the groups and that this may hinder the discussion in round two. Therefore, although not part of the original protocol, the facilitator decided to share with all participants the most recent nutrition guidelines at the time [2] and

three other key papers in the field.[130,164,165] These were sent by email soon after the first groups, with encouragement from the facilitator, for participants to read prior to the second round of groups. As per the protocol, at the commencement of round 2 and before the tape-recorded discussion took place, the facilitator shared with the participants by way of a short (10-15 minute) verbal briefing, the findings from the systematic review, and the initial findings from the patient interviews (Appendix 11).

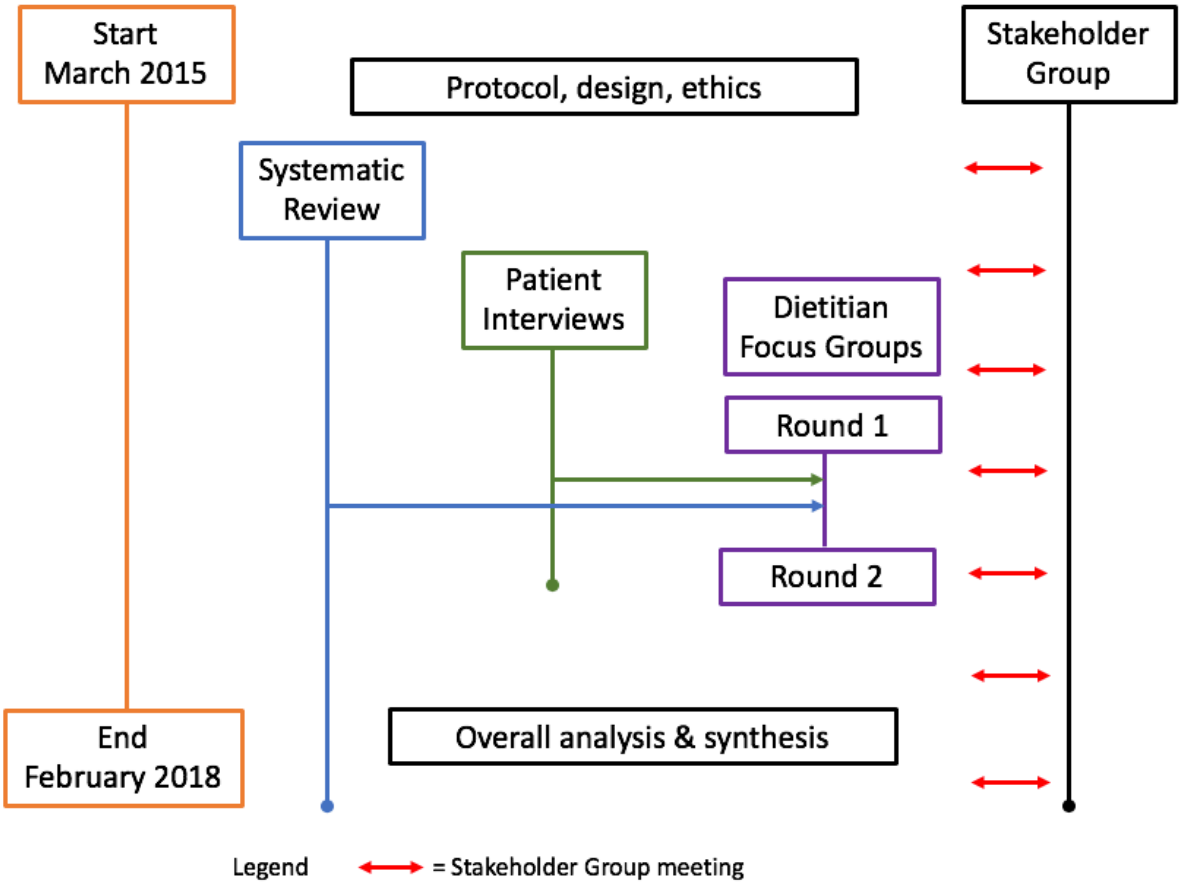


Figure 5 – Overall Study Flow Diagram

3.12.7 Analysis of Focus Group data

Thematic Analysis [106] was the method also applied to the Focus Group data. As with the interview data, the transcripts were checked against the audio recordings and cleaned to correct spellings of technical terms or when voices overlapped. The data from both rounds of focus groups were treated as separate data sets and analysed as such, so the resulting themes for each round of focus groups are separate.

The process of analysis matches that described for the patient interviews in Part One. First a process of familiarisation with the data was carried-out by reading and re-reading the entire data set. Then codes were attributed to sections of text to denote meaning, primarily in the form of semantic rather than latent codes. This was done across the data from all four focus groups from each round before grouping the codes into a collection of codes that share some conceptualized meaning in the form of a theme, identified by a 'central organising concept'. As with the patient interviews, research supervisors independently reviewed a sample of the FG transcripts and met as a team to agreed codes and develop themes. As described earlier, data saturation [134] was not the aim in the focus groups. Hancock *at al* [166] state that 'determining saturation for a focus group is challenging' and cites research that focuses on the importance how the focus groups are planned. In both rounds of FGs themes were developed after coding each set of focus groups in turn and saturation was reached for main themes after the third group in each round.

3.12.8 The Reflexive Researcher – Focus Groups

The researcher or facilitator of a focus group can have a significant impact on the data obtained from the group and its interpretation, not simply because of their skills in facilitation

or qualitative analysis, but due to their personal characteristics or status within the social context of the group. In this case, the facilitator was known in a professional capacity by several of the FG participants across all groups, either because of existing or previous working relationships, or by reputation and profile within a relatively small professional group. The facilitator has served on national committees, co-written guidelines and worked as a media spokesperson for The British Dietetic Association, meaning there may have been some pre-conceived views or opinions of the facilitator amongst some participants prior to the FGs. Whilst it is impossible to know for certain how this may have impacted the data obtained and subsequently the findings, it should be noted that it appeared advantageous in recruiting group participants and several shared the passion of the facilitator in their aim to improve how RDs advise patients with T2DM about carbohydrate. However, this also risked 'groupthink' whereby members of the group with alternative views may feel unable to disrupt the harmony of the group,[167] but this was not evident in the data. There is also a risk that those not known to the facilitator within a group which also included former colleagues or collaborators may have felt like 'outsiders' if they had noticed some participants knew the facilitator. Conscious of this, an effort was made not to engage in unnecessary small talk prior to the start of the FG discussion and to make sure all participants had the opportunity to contribute. It was felt that good facilitation skills and the use of ground rules would help to overcome this potential bias and effect on the data obtained.

3.13 Stakeholder Group & Synthesis

Research has clearly demonstrated there are measurable benefits to the inclusion of Patient & Public Involvement (PPI) in research including better quality research and improvements in recruitment,[168] however there are also challenges, such as the additional costs and time

taken to run such activities [169] and how the impact of PPI should be measured.[170] PPI activities are also at risk of suffering from the same power imbalance that they are intended to overcome.[171]

However, given the importance of PPI, a Stakeholder Group (SG) was established in the first 12 months of the research period and consisted of 3 patients with T2DM, a dietitian, a nurse, a GP, and a member of the public. The SG met 5 times over an 18-month period. Meetings were typically 1.5-2h in duration, were held on NHS premises and SG members were able to claim travel cots for attendance at meetings. Funding was made available for training and development of the SG members, either in the field of diabetes or with regards to involvement in research, however none of the members made use of this.

The themes from the patient interviews and the dietitian focus groups were taken to the SG for further interpretation, integration and synthesis with the aim of informing the development of a working definition of Carbohydrate Awareness Advice. In this context, the process of synthesis uses the evidence gathered to formulate advice that can be tested in future clinical trials. Incorporating the views of practitioners, people with T2DM and members of the public in this way has been suggested as a 'transparent, accountable process' that results in recommendations that are both practical and evidence-based.[172]

Themes for the patient interviews were shared with the SG in a meeting and two complete (anonymous) copies of transcripts from the patient interviews were also brought to the meeting. SG members were asked if they could identify the themes in the texts provided, and

whether they felt there were key themes missed or improperly represented in the analysis. Results of the SG involvement in the research process are presented in **Chapter Four**.

It is possible that the degree to which the SG was engaged in the research could have had an impact on the success and outcomes of the research. Therefore, consideration of the SG engagement formed part of the overall analysis of the results. SG engagement will be addressed in **Chapter Six** and will be based on the 7-item Stakeholder Engagement Reporting Questionnaire developed by Concannon *et al* [173] shown in **Figure 6**, below.

Figure 6 – 7-Item Stakeholder Engagement Reporting Questionnaire

Text Box 2. A 7-Item Questionnaire for Reporting on Stakeholder Engagement in Research

1. What types of stakeholders were engaged?
2. What were the a priori target number(s) for each type of stakeholder? Were targets met?
3. How was balance of stakeholder perspectives considered and achieved?
4. What methods were used to identify, recruit and enroll stakeholders in research activities?
5. Did engagement occur:
   a. before research began, during priority setting, topic development, question development, and research design;
   b. during research activities, including enrollment of patients, conduct of data collection, analysis, and interpretation of findings; and
   c. after research was concluded, including dissemination and implementation of findings, and evaluation of the research itself?
6. What were the intensity, methods and modes of engagement?
7. What, if any, was the impact of stakeholder engagement on:
   a. the relevance of research questions;
   b. the transparency of the research process; and
   c. the adoption of research evidence into practice settings?

This figure presents a list of questions that may be used by researchers to guide future reporting on stakeholder-engaged research. These questions were co-developed with a stakeholder panel

CHAPTER FOUR

RESULTS OF PATIENT INTERVIEWS & DIETITIAN FOCUS GROUPS

4.1 Introduction

This chapter presents the results from the two qualitative components of this thesis; the patient interviews and the dietitian focus groups. The findings and analysis from the patient interviews are presented first, followed by those from each of the two separate rounds of focus groups. A summary the findings is provided at the end of each section and an overall summary at the end of the chapter.

4.2 Patient Interviews

4.2.1 Sample demographics

Participants were recruited from a database of 314 patients, as described in **Chapter Three**. Table 6 summarises the key demographics of the participants and provides a comparison to the demographics of the whole database from which they were recruited, in an attempt to demonstrate whether there was any selection bias. The sex distribution of the patients in the database suggests a small majority of female patients and an ethnicity profile which is not dissimilar to the wider population of Birmingham, the city in which the research was conducted.[174]

Table 6 – Demographics of sample vs. entire database

	Entire database (*n* = 314)	**Participants (*n* = 15)**
Male *n* (%)	147 (46.8)	9 (60)
Female *n* (%)	167 (53.3)	6 (40)
Age (y)		
Mean Age (range)	57 (21-95)	62 (40-82)
Ethnicity *n* (%)		
White British, Irish & Other	168 (53.5)	9 (60)
Asian or Asian British	93 (29.6)	3 (20)
Black or Black British	28 (8.9)	2 (13)
Mixed or Other	9 (2.8)	1 (7)
Chinese	0	0
Other & Not Stated	16 (5.0)	0

4.2.2 Participant Characteristics

Participant characteristics are summarized at an individual level in Table 7. Participants comprised a diverse range of patients with regard to their duration of diabetes and the number of RD contacts they had received in the previous 2 years. There were some differences in the demographics of the participants compared to the database of patients from which they were recruited (Table 6). The participants were slightly older, included more males, and there was an under-representation of Asian or Asian British participants in comparison to the population from which the sample was drawn. All those that were interviewed spoke English and did not require an interpreter. Most of the participants were

retired or unemployed, which may represent a bias in sample selection since the recruitment telephone calls took place mostly during office hours (08:30 – 19:00) as these were the working hours of the researcher, although flexibility was offered with regards to the timing and location of the interviews. One interview took place early evening to allow the interviewee to finish work prior to the interview

Table 7 – Individual participant characteristics

Participant Number	Gender	Age[a] (years)	Ethnicity	Duration of T2D (years)	Number of RD contacts[b]
P1	F	65	Black / Black British - Caribbean	11	10
P2	M	73	Asian / Asian British - Indian	3	7
P3	M	50	White British	7	3
P4	M	49	White British	2	5
P5	F	63	White British	8	3
P6	M	55	Asian / Asian British - Pakistani	21	2
P7	F	64	White British	8	5
P8	M	43	White British	<1	3
P9	M	64	White British	17	9
P10	F	40	Mixed - Other	9	6
P11	M	72	White British	8	5
P12	M	68	White British	6	9
P13	F	82	White British	9	2
P14	M	57	Asian / Asian British - Indian	3	1
P15	F	82	Black / Black British - Caribbean	5	2

[a] age at enrolment

[b] in previous 12-24 months

4.2.3 Structure & Presentation of themes

The analysis of interview transcripts from patient interviews resulted in the development of 3 overall themes, with 10 additional sub-themes (Table 8). Several of the sub-themes are

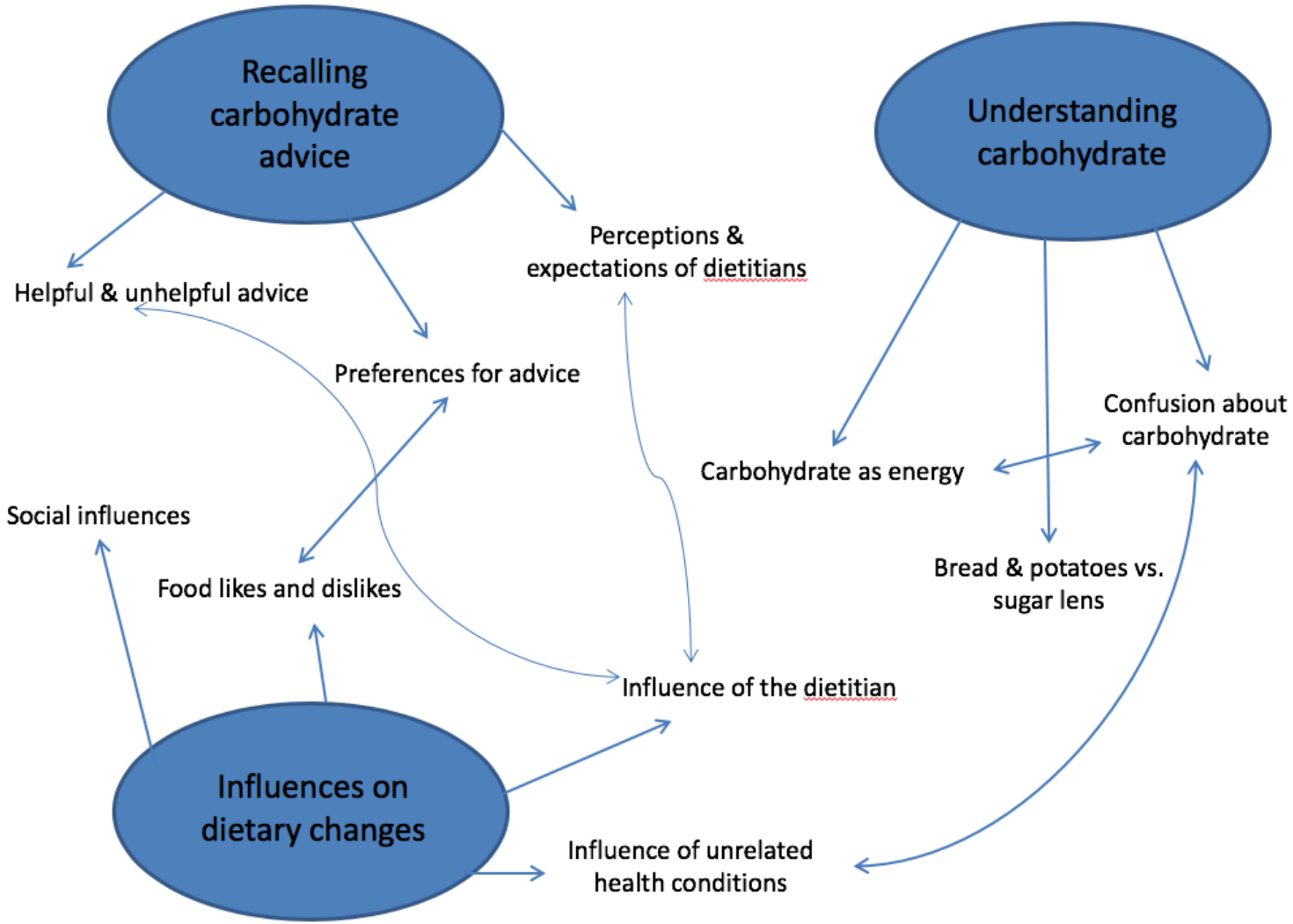
interrelated or overlapping, which is not uncommon in thematic analysis [175] and this is shown in **Figure 7**.

Each theme is first summarised and then supported by excerpts of data to provide evidence for that theme. Further explanation of the key elements of each theme follows, together with additional excerpts from transcripts to illustrate how the data contributed to the theme development. In places, multiple excerpts have been used in succession to highlight the degree to which participants reported similar views or experiences.

Table 8 – List of themes and sub-themes for patient interviews

	Main theme		**Sub-theme**
1	Recalling Carbohydrate Advice	1A	Helpful & unhelpful advice
		1B	Preferences for advice
		1C	Perceptions & expectations of dietitians
2	Understanding Carbohydrate Advice	2A	Carbohydrate as energy
		2B	Confusion about carbohydrate
		2C	Bread & potatoes vs. Sugar lens
3	Influences on dietary changes	3A	Influence of the dietitian
		3B	Influence of unrelated health conditions
		3C	Food likes and dislikes
		3D	Social influences

Figure 7 – Thematic Map (Patient Interviews)



Theme 1: Recalling Carbohydrate Advice

This theme describes participants' recollection of the advice they received, including advice from non-dietitians. The sub-themes focus on whether patients found the advice helpful, their preferences for advice and their perceptions of dietitians.

Advice from dietitians as recalled by participants varied widely and was typically vague in their initial recollection, but there was repetition in several areas; particularly around amounts of food or portion sizes and timing or regularity of meals.

> *"And she told me that it was important to have three meals a day and cut it out – the grazing – and the sampling and so on. And that's made a massive difference."*

[P12]

Participants tended to have a generally positive or neutral regard to the recollection of the advice received, with only one participant reporting purely negative opinions of the advice. Some participants had difficulty in articulating their opinions and their experience regarding the advice received from the dietitian, giving quite short responses even after further prompting. This could be simply due to poor memory as found in other research,[176] perhaps related to the duration of time elapsed since receiving the advice or to a sense of apathy regarding the advice and overall experience of consulting a dietitian.

> *"Well, err, she was a great lady and, err, gave, like, umm, instruct me very nice way, and, umm, we were talking about, err, portion control."*

[P2]

Advice recalled by patients ranged from general advice to reduce portions to quite specific advice about the timing of meals, quantities of food and the balance between the proportions of different food groups. None of the patients interviewed recalled advice from the dietitian about specific quantities of carbohydrate, whether in terms of grams of carbohydrate or even in the form of household measures of portion sizes.

There was even uncertainty from some of the participants interviewed that the professional they had seen in consultation was in fact a dietitian. Prior to each interview it was verified using their medical records that they had received one to one advice from a dietitian but, in some cases, they perceived the dietitian to play a relatively minor role in the consultation, when it was conducted jointly with another health professional (usually a diabetes nurse).

"But now thinking about it, he was involved in the discussion. But the discussion was led by [name], the diabetic specialist [nurse]. Looking back, there wasn't much of an input, in terms of food intake, by the gentleman who was present in the meeting. The discussion was primarily based around my blood sugar levels with the diabetic specialist nurse."

[P6]

One participant felt there was very little advice given but then recalled later in the interview the dietitian had reassured her that what she was eating was appropriate.

"And she said what type of food do you eat? Which I told her, which she said was alright. And exercising which I was doing."

[P13]

Other participants recalled advice that was based primarily around the balance of the main macronutrients: carbohydrate, fat and protein, and this seemed to match their level of understanding of nutrition. This might reflect dietitians establishing the existing knowledge of patients before determining the language or terminology they use with individual patients, since some patients reported the term 'carbohydrate' was not mentioned by the dietitian.

"Whether I was taking sufficient protein, carbohydrate and the balance, the mix of my foods, was basically reviewed, in terms of carbohydrate intake, in terms of fat intake, in terms of protein intake. That was what was discussed."

[P6]

Advice from non-dietitians came from a range of sources including other health professionals such as the patient's GP, practice nurse or diabetes specialist nurse. However, in some cases participants recalled advice they had received from friends or acquaintances, and there was a suggestion that this advice was given greater credibility where it may have been based on the personal experience of someone known to the patient.

"I had a jacket potato and it was a very large one, and I thought I don't have to have anything else with it because it's, it's, it's enough. It's, you know. But then there was a, a nurse, she used to be a nurse and she retired and she says to me, erm, [Name], don't eat that."

[P1]

Many participants talked about the advice from the dietitian and the dietary changes they had made in a sugar-centric context, particularly in relation to fruit and its sugar content. There was a sense of confusion and uncertainty throughout this topic which suggests either an incomplete understanding or recollection of the advice, or that the advice given was itself focused on sugar; which is unlikely given the nutrition guidelines for some 8 years have not made specific recommendations about sugar.[2] Interpreting or recalling the advice through this sugar lens may suggest the understanding of the overall message was not sufficiently conveyed or received, or that the dietitian did not routinely explore the patients' understanding of the advice given. Patients may also have pre-conceived ideas about the nature of advice, which in turn influences their interpretation and recollection of what is said.

"Well, stuff with lower sugar in I would go with, I know the fruits got more sugar in it, natural sugars in it… So, I think your body needs a certain amount of natural sugars, but if you have too much of it then you…if you get too much sugar in your body then that will affect diabetes."

[P3]

"Like with sugar …I do admit I have sugar in coffee but I only have one now. I used to have two. We don't have it in tea. Um, it's like you're always looking at labels when you go in the shops, seeing what's in them and then realising that it's not only sugar, there's other kinds of sugars in things. And I can't remember what they're called now. And things like fruit, it contains natural sugar."

[P6]

"But I was having too much fruits and fruit's got sugar in, so I was keeping away from putting sugar in me tea. But I was eating a whole lot of fruits. And that wasn't good enough for me, in that way."

[P15]

Theme 1 (a): Helpful & unhelpful dietitian advice

All but one of the participants reported they found the advice from the dietitian helpful, and even when participants felt they already knew what to do, it was reassuring to have the support of the dietitian and in particular where they recognised the challenges patients face in making dietary changes. This also suggests that some patients lack confidence in making dietary changes without the support of a healthcare professional.

"but she said, that's okay, you know, but if you do relapse then fine. Don't feel...don't beat yourself up about it sort of thing. And that was so reassuring. And so nice that, you know, that both ladies acknowledge they're human."

[P12]

"I think reassurance, further guidance. Wasn't the most vocative person, he tended to sit and listen to what I was saying."

[P9]

Several patients recalled advice about specific foods, portion sizes or quantities of foods and many stated they were advised 'what not to eat', which suggests didactic advice was given, despite this not corresponding with the typical approach dietitians would take. Their recollection appears to be framed by some pre-conceived ideas about the type of advice

dietitians provide, even after having experienced it, as reflected by their language. For example, words and phrases such as ‘should’ and ‘shouldn’t’, ‘cut out’ or ‘damaging’ are used by patients to recall the advice.

“…what to eat and what not to.”

[P1]

“…the dietitian was telling me more or less about what I should and shouldn’t eat….”

[P5]

Patients who referred to experiencing a positive outcome tended to describe the advice as helpful and related their success to the advice of the dietitian.

“I mean I benefited from it. I've lost weight. I feel a lot better in myself, more or less the advice [the Dietitian] give me, if you know what I'm saying?”

[P4]

One patient described the advice as helpful but having also created a strong sense of guilt around eating as he is now more conscious of his food choices. It is notable that none of the other participants referred to any strong emotional responses in relation to their attitudes to food as a result of the advice from the dietitian.

"Reassuring and helpful but, as I say, I come back to what I said about I have...who knew that food could be so guilt-ridden? I feel, you know, really genuinely guilty about anything that passes my teeth now."

[P12]

Other patients talked about the importance of being listened to and one reflected on how the accumulation of advice 'like a jigsaw' over many appointments led to their improved understanding, perhaps emphasizing the importance of multiple visits to the dietitian. This corresponds with the literature which suggests greater effectiveness is associated with more contacts [177] and that maintenance of behaviour change is more likely to occur in interventions delivered over a longer period.[178] It also relates to the importance of developing a rapport in order to achieve a successful therapeutic relationship.[179]

"It was partly the approach but it was the, if you like, jigsaw puzzle. You know, I'd go on one visit and I'd get a couple of pieces there and then I'd get a couple of pieces there, then my brain would think, if you put that and that and that, and cross reference everything. So, it comes towards what I am doing now as far as that's concerned."

[P09]

Reasons for why participants felt the dietitian's advice was found to be unhelpful included the feeling of being judged or patronized; having multiple dietitians involved in their care; a high level of existing knowledge which is unrecognized by the dietitian; and where the patient did not achieve the desired outcome, such as weight loss. One participant commented on how the advice was practical, even obvious in nature, but then was still unable to lose weight

and therefore deemed the advice from the dietitian 'unhelpful', which suggests somewhat of a contradiction and that something was missing from the advice, but which they were unable to identify or vocalise themselves. This implies that the patient places the responsibility squarely on the dietitian to establish what the patient needs to succeed and to provide this in a transactional manner, rather than as a therapeutic working relationship. It also implies there is something less obvious the dietitian needed to identify as part of this process of assessment and offering information or advice.

"Well the information they offered was practical and common sense, you know, even a ten-year-old child could work it out, but I didn't find it helpful because I didn't lose any weight."

[P11]

One patient described advice that was based on drawing 'little circles' and 'imaginary plates' which he felt was unhelpful because it did not take account of his prior understanding of the topic or what he wanted, implying that the dietitian was both patronizing and not tailoring the advice to his needs. Rather than explaining to the dietitian that this was not what he wanted, the patient decided not to return to the dietitian. The suggestion that patients may be unable or unwilling to articulate their needs or preferences in their interactions with the dietitians, and would simply rather not return, is an important finding that could influence how dietitians might approach consultations with patients differently.

"…but the woman was drawing little plates and can you draw little circles and I thought no, this isn't for me. I left and because, you know, I hope I'm

not being arrogant by thinking I was a bit better than drawing circles on imaginary plates."

[P12]

Advice was felt to be unhelpful if it appeared to be repetitive, if it was information the patient already knew, or if the patient did not lose weight as a result. One patient had seen 5 different dietitians as part of their care and felt this lack of continuity affected the quality of the advice.

"But mostly it's common sense, and they just repeated what you already know…"

"The other thing was, I had five… I think it was five different dietitians, not the same one… Well there's no flow, you know, I mean if you talk about something...like if I saw you next time, I'd know exactly what I'd said to you, and you'd know what you said to me, and it would flow on a bit more."

[P11]

Some patients referred to specific foods being 'pushed' by the dietitian, such as nuts and fish, whilst also stating they did not intend to follow that advice, suggesting that the dietitian did not establish food preferences and the patients' intentions with regards to the advice offered.

"[The Dietitian] tried to push me to eating nuts. Don't do it, I just don't like nuts."

[P09]

Theme 1 (b): Patient Preferences for Advice

Participants talked about both the form of the advice they would prefer (e.g. written vs. verbal) and more specific elements of the advice; such as wanting didactic advice about specific foods, practical advice or advice tailored more appropriately to the whole family or their specific culture. There were mixed views about how simple or complex advice should be, but participants valued continuity (having the same dietitian for follow-up) and disliked being made to feel as though the dietitian lacked time for the patient to ask questions.

There was no consensus amongst participants about whether they wanted advice to be in a verbal or written form, with both being expressed as helpful and a suggestion that the written information provided should act as a resource for patients to refer back to and remind them of the conversation, or to provide more detailed information for them to study at a later time, after the consultation.

"If they'd have given us a leaflet or a book or something, then I could have brought it home, because by the time I got home, I'd forgotten half of what they said."

[P3]

"I think what it is… is sometimes when the dietitian explains something, if you've got an exact written thing as well then… I probably could understand it if I read it more, if I kept reading it and read it more clearly."

[P5]

Explanations that are both simpler but more comprehensive were requested by some patients. The term carbohydrate was felt to be a helpful word but one which requires further explanation by dietitian.

" It's a helpful word… but it needs to be explained more…more in-depth 'cause I don't think people understand actually what carbohydrates is. I don't think it's sometimes made clear enough and simple enough for people to understand. That's the hard part. It's not being made simple enough."

[P5]

There was a desire for practical support or for making the advice more visual, such as the use of pictures or photographs. One participant described a desire for quite specific, didactic advice from their dietitian, which suggests they may not have not taken ownership of self-management of their condition and would rather leave the decision-making to their health professional. This same participant also referred to dietitians negatively and as an ineffective resource.

"Cooking and things like that, try different ways of cooking things to help with diabetes and things like that."

[P03]

"If I can see a list, say Monday morning you eat this, you drink this, Monday lunch time you eat this, you drink this, and so on, that would have been more help… I think if you saw...like you've got some pictures there I noticed, of food. If you put that in a...that for breakfast, that for dinner, and so on, and that would be a bit more beneficial… more

practical...practical things. I mean they're not...they're not passing on advice by talking."

[P11]

Some patients referred to the need for culturally-specific information or approaches targeted at a community-level in order to influence changes at a both family and individual level. In one case the respondent felt that the dietitian lacked an understanding of their diet and of the nutritional contents of specific cultural foods included in their diet, which was a barrier to them feeling adequately supported.

"I think the dietitians need to be somewhat more aware of different diets. And when I say different diets, I'm at the risk of being...somewhat introducing race into it, culture into it. Because being of the ethnic minority, my diet is somewhat different, to say the least, from the indigenous residents of the UK, in terms of bread. There is no information out there, what a chapatti does, what a roti has, what a naan bread has and what a paratha has… There is no information out there, unless you're buying these items in prepacked, precooked and somebody has taken the time to put on the packet, fine…"

[P6]

Other participants highlighted the importance of working at the community and family level to overcome barriers individuals face in making changes. In the quotation below, the respondent also explained that many meals are taken in the religious centre and the preparation and cooking of these meals is done by different families who take turns to do so. Therefore, advice focused on the individual was felt to be ineffective.

"I think they need to go into the community, right, where it would be more helpful, because you'll have a lot of people there, you could have a lot of views there, and you could actually experience what they're eating and how it's being cooked and prepared. So, I think that would be a good thing…"

[P14]

One participant with an un-related health condition felt there was a lack of integration of his care between the two types of specialist dietitian he had seen, despite having made this clear to them at the time. There was a strong sense of frustration which was linked to doubt the patient held that the advice for one condition would not be contradictory for the other.

"What I would ideally like, is the two dietitians, the diabetic dietitian and the dietitian at the liver unit, should sit down together and communicate… There's no joined-up thinking. She's focusing on my situation regarding my digestion of food and the other dietitian probably looked at the diabetic aspect of my diet."

[P6]

Theme 1 (c): Patient Perceptions & Expectations of Dietitians

Despite an overall positive perception of dietitians, there were mixed feelings about them, ranging from surprise over how helpful and knowledgeable the dietitian was, to criticism of their specific (lacking) knowledge of cultural foods and eating patterns.

One patient explained how the psychological support she accessed because of the dietitian had radically changed her outlook on life, whilst another described the positive impact of

having someone who can listen and who understands why people eat. This suggests a degree of trust in the professional expertise and the confidential nature of the relationship between the dietitian and the patient, and that the role of the dietitian is much broader than simply giving advice about food or dietary changes.

"…and, you know… So basically, the dietitian has made me want to live, like make me happy …and make me feel alive, if you know what I mean."

[P5]

"Sometimes I say, oh, I'm sorry, this month I was so naughty, I eat those kinds of things, I like to have someone to talk to. That kind of thing, not going to talk to my husband or my family, I like to talk to someone who understands what I feel…because I think that the dietitian understand why people are eating."

[P10]

One participant highlighted that their experience with the dietitian(s) was more positive than expected, particularly taking into account how weight is portrayed in the media in the sense that there is a blame culture targeted towards the individual, which he did not experience with the dietitian(s). For this participant this was also within the context of a previous negative experience of dietitians, which highlights the strength of this positive attitude given the potential for prejudice or bias based on previous experiences.

"I've found both ladies motivational. Very much so. You know, not condemnatory in any way."

[P12]

Where the dietitian established the patient's existing understanding and targeted the advice at their needs, there was a clear positive reaction, which implies that this is not the typical experience or expectation of people who consult with a dietitian. In fact, one participant specifically referred to returning to see a dietitian after a previous experience with a dietitian that did not adopt this approach.

> *"So, when I went back and saw [Dietitian's name], it was an absolute eye-opener because I was treated like an intelligent adult for a start and that was refreshing and a bit more what I was after."*

[P12]

Two participants explicitly criticised the dietitians' apparent lack of knowledge, understanding or awareness of cultural practices and the nutritional value of foods specific to their cultural background, which they felt hampered the dietitians' ability to help them make dietary changes. This may represent cultural barriers between the professional and their patient, or it could be a matter of poor communication on the part of the dietitian. The dietitian may possess this knowledge or understanding but did not convey that understanding to the patient in a manner which the patient could be confident of the dietitian's abilities to help them. This also highlights, as with other examples, the expectation of the relationship between the dietitian and the patient, from the patient's perspective. They may perceive the relationship as an asymmetrical 'expert-novice' relationship whereby the dietitian holds the knowledge and power and the patient takes as a passive role.[180] This idea runs contrary to the principle of 'patient-centred care' which is widely promoted and highlighted in national

guidance as the recommended approach in supporting people to make lifestyle changes in long term conditions.[181]

"I felt that the specialist was somewhat ill informed or lacked knowledge in the variety of the diet that an ethnic person would take. And their, how shall I put it, knowledge of carbohydrates…"

[P6]

"They don't understand the Indian food, you know, how it's being cooked, or how we sit down and share the food. You know, it's a lot difficult for us; it's difficult just to say, well, that's my portion, and you eat your portion."

[P14]

One interviewee held particularly negative views of dietitians (amongst other health care professionals), literally stating that they were a waste of NHS resources, which may be related to many years of failed attempts at changing his diet to lose weight. He also criticized the repetitive nature of the different services he attends.

"One of the questions, 'why do you think you're putting on weight'? Because I'm bored. 'Have you thought about buy a colouring book? That was one of the things."

"In other words, I think the dietitians, in this case, they're wasting their time, and the National Health's money."

[P11]

Theme 2: Understanding Carbohydrate

This theme describes how patients understand carbohydrate and identifies some distinct but related sub-themes which highlight the three key aspects of understanding which were found in the data.

Understanding of carbohydrate varied widely amongst participants, and their comprehension of the subject was very tentative, however there were common concepts which were shared by most of the patients interviewed. This suggests that, despite some uncertainty regarding definitions or precise messages around carbohydrate, patients did possess a common understanding principally regarding carbohydrate as a form of energy and a general perception that eating too much carbohydrate would have negative consequences.

"I don't really know, it's carbohydrate that turns to sugar, isn't it?"

[P4]

Theme 2 (a): Carbohydrate as energy

Many of the patients interviewed were familiar with the idea of carbohydrate being a source of energy and used this word to describe their understanding of what carbohydrate is and how it functions in the diet. Some patients understood the consequences of eating too much carbohydrate [positive energy balance] yet did not use the same terminology, as below. Participants with a better understanding tended to associate carbohydrate foods with increasing weight.

"Well, oh, that word. I know it's got something to do with your erm…I can't, I can't remember that one. But I know it's…it, it's very… If you eat too much of it well, I know it erm, it, it…it makes…you put weight on."

[P1]

The concept of carbohydrate as an energy source had both negative and positive (or neutral) elements from different participants. Some patients acknowledged that the energy from carbohydrate can be stored or used, however not all mentioned the link between carbohydrate intake and blood glucose response, which is a key concept in the dietary management of diabetes.[53]

"Well, carbohydrate, err, is…produces energy…err, if that energy is used, then it's beneficial but if it is, err, stored, that is not very good. That increases the weight, that's what I tried, but I'm told the different things…"

[P2]

Theme 2 (b): Confusion about carbohydrate

Despite carbohydrate being a key nutrient in diabetes, several participants stated that the dietitian did not mention the word carbohydrate as part of their consultations, or they struggled to recollect the conversation and therefore the significance of carbohydrate in T2DM. Even where participants recalled carbohydrate being discussed, they still felt further explanation was needed, suggesting the explanation was incomplete or unmemorable for some reason.

"…but it's not been explained. I don't really understand carbohydrate, what that means. If they explained that a bit more, I'd probably be aware, but I'm not too sure what that is."

[P14]

The tentative nature of patients' understanding is highlighted again in the example below. It is possible that the word 'carbohydrate' itself becomes some form of barrier for some patients to possess a level of confidence in their own knowledge, since it could be perceived as a highly technical or scientific word in the context of managing their diabetes, despite it being part of the vernacular used in the press and popular dieting industry for many years.

"I don't really understand it. I know it can… Carbohydrates is like, I suppose it… Is it one of those that gives you energy and stuff and you need it for the energy, but you only need a certain quantity? I'm not really sure.''

[P5]

Theme 2 (c) 'Bread & Potatoes' & the sugar lens

There was widespread uncertainty over the meaning of carbohydrate with almost a universal understanding that it includes 'bread and potatoes', suggesting that patients frame their understanding of nutrition in the context of specific foods or examples of foods. Even patients who gave an accurate account of the meaning of carbohydrate hesitated, expressed self-doubt and were seeking confirmation from the interviewer. The concept of carbohydrate foods providing energy was widely reported and, in some cases, this was associated with labelling carbohydrate foods as either 'good' or 'bad'. Participants with a better

understanding tended to associate carbohydrate foods with increasing weight. Some participants made the link with carbohydrates 'turning into sugar' which is likely a reference to their potential to affect blood glucose and, although not all participants demonstrated this awareness, those that did also had an incomplete understanding.

"That's, erm, bread, and that, isn't it, carbohydrate?
I don't really know, it's carbohydrate that turns to sugar, isn't it?"

[P3]

"That never sunk in. Er, I put it down to potatoes and breads and rubbish food as crisps, bread, potatoes, all that, you know…"

[P4]

"It's like bread, potatoes… That's about all I know in carbohydrates."

[P7]

One participant demonstrated scientific knowledge when describing their understanding of carbohydrate, later referring to their educational background to explain their understanding of carbohydrates.

"Well, carbohydrates are basically carbon, oxygen, hydrogen, and it's like you can have monosaccharide, disaccharide, you can go right up to starch."

[P9]

Despite carbohydrate being a key nutrient in diabetes, several participants stated that the dietitian didn't mention the word carbohydrate as part of their consultations, or they struggled to recollect the conversation and therefore the significance of carbohydrate in type 2 diabetes. Even where participants recalled carbohydrate being discussed, they still felt further explanation was needed, suggesting the explanation was incomplete or unmemorable for some reason.

"Not really, no, 'cause I mean they expected you to know that. I mean...no they didn't, no. They did nothing. Nothing like that."

[P11]

"…but it's not been explained. I don't really understand carbohydrate, what that means. If they explained that a bit more, I'd probably be aware, but I'm not too sure what that is."

[P14]

In contrast, it appears that participants who received much more specific advice about carbohydrate, including some information about quantities, were better able to recall and apply that advice to their own diet.

Theme 3: Influences on Dietary Changes

This theme explores the range of influences on dietary changes and food choices. It largely relates to the data derived from the scenario activity in which participants were asked to select a food from a range of photographs and then talk about why they made that choice.

Overall, there was some contradiction within the interviews about the factors that influence food choices, with several participants suggesting that the interactions with the dietitian had little influence on their food choices, yet at other points in the same interview describing changes they had made and attributing these directly to the dietetic intervention. Other health conditions, the influence of family, spouses, employment, personal experience ('what works') and to a lesser extent the media or other sources of information were also cited as influencing food choices or dietary changes. Not all influences were observed in each participant, however influences came from three distinct areas, resulting in the three themes outlined in this section:

- **Theme 3 (a): Influence of the dietitian** relates to the direct and indirect impact of the advice given during consultations with the dietitian.
- **Theme 3 (b): Influence of unrelated health conditions** describes how motivation to make dietary changes was enhanced by a more pressing but often un-related condition which impacts on daily activities and quality of life.
- **Theme 3 (c): Social and other influences** describes the cultural and family impacts on patients' ability to implement the advice they have received, highlighting this as a conflict experienced by patients.

Theme 3 (a): Influence of the dietitian

The sugar-centric approach to food choices re-appears when participants articulate why they had selected particular foods from a selection of images presented during the interview, and rarely did they credit the dietitian or the advice they had received from their consultations for influencing their choices in this exercise.

"Because there's not a lot of sugar in and stuff like that, you know…"

[P13]

However, one patient was clear in stating that changes in food choices were as a direct result of the dietetic intervention.

"What before? Well I go and take a big chunk of cake, a cuppa tea, or a glass of orange squash or anything. That's what I would go for. Definitely."

[P15]

Theme 3 (b): Influence of unrelated health conditions

It was clear that other health conditions were a strong factor affecting dietary changes. One participant felt that their diabetes was having very little impact on their quality of life or food choices prior to an (unrelated) surgery, which then resulted in the need for specialist dietetic advice for both aspects. There is a sense that a conflict was created between the priorities for managing both dietary approaches, meaning there need to be some form of re-prioritisation of dietary changes for the patient.

"My issues, prior to my surgery, were normal, in the sense I was coping and I was managing without interference, in terms of specialist dietitians or nurses. Coping fine. But since my operations, it has become an issue."

[P6]

Another patient found that a more pressing dietary-related condition required immediate changes to his diet in order to continue with his daily activities, including employment. There

was a serendipity that the dietary changes required for the immediate resolution of symptoms for the other condition, were also beneficial changes with regards to diabetes management. The idea that diabetes is a 'silent' condition; that is, there are often no obvious symptoms resulting from dietary indiscretion and the complications are seen as a distant risk rather than something impacted by day to day food choices, is an important consideration for achieving behaviour change.[182,183] This excerpt exemplifies this change in focus and resolution of ambivalence regarding dietary changes, once there is a perceived urgency and potentially immediate benefit from changing.

"…but I didn't really take much notice of it, you know, you know what it's like, I'm…I'm alright, you know, I'm alright, until something like this happened or something like what has happened and then I had to cut everything out and it's made…it has changed my diet a lot and the odd day I cheat."

[P3]

The conditions that appeared to influence dietary changes have in common that their effects or symptoms are more immediate or perceived more gravely than T2DM. None of the patients interviewed cited symptoms of high blood glucose or a fear of the long-term complications of diabetes as part of their rationale for making food choices. When faced with an immediate choice of foods it appears that preference was the principal driver in many of the participants. This aspect of the diet did not appear to have formed part of the advice or discussion with the dietitian, as recalled by the patients.

Theme 3 (c) Social & other influences

The impact of family and culture were highlighted by participants in having an impact on the types of meals they eat, essentially saying that they'll eat what the rest of the family eat rather than prepare something specifically designed around their dietary needs. This suggests the participants believe they should be eating food that is less appealing to the rest of the family, creating a barrier to the whole family eating the same way and a conflict between what participants believe they *should* be doing, versus what they are actually able to do.

> *"It is sometimes making the choices but sometimes then you're cooking for other people and you don't want to have to prepare two different meals and you just think to yourself, oh, I can't be bothered. And then when you get like that, you just think to yourself, oh, I don't… You start thinking, well, I'll have what they're having."*

[P5]

Other aspects of this theme included the cost of healthier versions of ingredients and cultural factors affecting family food preferences, such as in Asian families in the excerpt below. There is also a sense of dichotomous thinking regarding dietary changes, suggesting an either / or and 'all-or-nothing' approach which could be addressed though the dietetic assessment and advice offered by the dietitian, if dietitians were aware of this experience.

> *"It's very difficult for Asian people to get it spot on, because of the families. The kids – if we make something and it's bland, they'll not eat it, and that means, then, we have to do separate cooking for ourselves, and separate for them, which means more work….*
> *We find it costs a lot of money to buy a little tub of butter, you know –*

things like that. They do matter, but, you know, it's just hard to cope with it. We can't just do it for ourselves; we do it as a family."

[P14]

Finally, a recurring theme in response to the questions regarding the influences over food choice is preference and habit. These appear to be stronger drivers for patients than any advice they may have received from dietitians or other health professionals. When asked what led to their decisions to select from a wide selection of foods, responses included "*That's what I normally eat*" [P11] and "*Because they're digestives. I like them*." [P7] and "*It's just what I like.*" [P3]. The idea of choosing foods that patients 'like' as a justification appears to be socially and contextually acceptable in the interview scenario. Although some participants did enter a dialogue with themselves regarding the competing rationale behind their selection, ultimately the preference was a more important factor than the perceived nutritional or health benefits. Patients would rarely select a food they did not like purely because they believed it to be the healthier option.

4.2.5 Summary of patient interviews

A generally positive regard towards dietitians and the advice they provided was found amongst the interview participants, which may be indicative of a selection bias in the sample. In fact, at least one participant overtly expressed a desire to 'help' by agreeing to be interviewed and as a form of gratitude for the service they had received, suggesting a form of altruism that has been reported elsewhere in the literature.[184] This may have also been the case, but was not expressed, in other participants. Those who had a less positive experience may have declined the opportunity to be interviewed. However, given the size of the sample,

it reflected reasonably well the demographics of the population from which it was drawn in all but one aspect, as there was a bias towards male participants being interviewed, which may be related to the interviewer being male, something participants would have become aware of at the recruitment stage.

In accordance with the general positive regard, there were more reports of advice that was found by participants to be helpful rather than unhelpful. Despite the language used by participants reflecting a dichotomous thinking approach to food, which dietitians typically avoid, they found advice of 'what to eat and what not to eat' useful. This implies either they had a better recall of the more specific advice, perhaps relating to individual foods, or simply that they have framed their recollection of the advice within their pre-conceived ideas and expectations of what a dietitian does, irrespective of the actual experience.

Participants found advice unhelpful if it was patronising, repetitive or did not take sufficient account of their preferences or their social and cultural environment. Participants found advice helpful if; it took account of their previous knowledge, addressed their needs and preferences, was reassuring and involved the dietitian listening, and if the patient achieved their desired outcome. The data from the interviews suggests that dietitians are at risk of patients disengaging with treatment rather than verbalising their dissatisfaction, should the dietitian not address the wishes and preferences of the patient clearly enough and throughout the period of care, rather than only at the initial assessment.

4.3 Dietitian Focus Groups

A total of 4 focus groups were held in four U.K. locations: Birmingham, London, Glasgow and Cardiff (see section 3.12.3, page 48 for justification). Each focus group consisted of between 3 and 8 participants and included Dietitians of varying amounts of experience and levels of seniority. The focus groups were carried out in two rounds, with the same cohort of participants, each with a different aim.

4.3.1 Participant Characteristics

Table 9 describes the characteristics, including the socio-demographic composition, of the RDs who took part in the focus groups. With regards to the gender distribution, approximately 8% of the sample were male, which is slightly higher than the dietetic profession as a whole, estimated to be 5.2% male in 2016.[185] It is assumed that the age distribution was also fairly representative of the profession, since data are not readily available. There were differences in the ethnic diversity within groups, likely explained by the differences in demographics of the locations in which they were held. There were also differences with regards to the proportion of participants who identified as a Diabetes Specialist Dietitian (DSD), with the London group including the highest proportion of specialists and Glasgow the fewest DSDs. The average years of experience as an RD (and range) were comparable across all groups except for Birmingham, which is likely due to the low number of participants in that location.

Table 9 – Characteristics of RDs in Focus Groups

	Gender (n)		**Ethnicity**	**Age** (n)					**Diabetes Specialist** (n)		**Experience as an RD** (years)	
	Male	**Female**	**% White British**	**18-24**	**25-34**	**35-44**	**45-54**	**55-64**	**Yes**	**No**	**Mean**	**Range**
Birmingham	0	3	66.6%	1	1	1	1	0	1	2	8.7	2-18
Cardiff	1	5	83.3%	0	2	1	1	2	3	3	16	2-30
Glasgow	0	8	87.5%	0	2	4	2	1	3	5	16	6-41
London	2	5	57.1%	0	2	1	2	2	5	2	15	5-35

4.3.2 Round One Focus Groups

As outlined in **Chapter Three**, the purpose of the first round of focus groups was to explore and describe how dietitians currently practice with regards to carbohydrate advice, and what influences how they advise patients with T2DM about carbohydrate. Two main themes were developed with four sub-themes.

Table 10 – List of themes and sub-themes for round one RD focus groups

Main Theme		**Sub-Theme(s)**	
1	Dietitian's Aims, Individualisation & Pre-Advice	1a	Dietitians as professionals and disagreements between RDs
2	The role & importance of carbohydrate advice	2a	Types of carbohydrate advice given
		2b	Determinants of specific carbohydrate advice
		2c	Meaning of carbohydrate awareness advice for RDs

Theme 1: Dietitian's Aims, Individualisation and Pre-Advice

Dietitians stated that addressing patient perceptions, expectations & dealing with previous inaccurate advice is important. Dietitians described the route via which the patient arrives, and the advice given to them prior to seeing the dietitian, as important considerations for how they will approach their initial advice and consultation with patients. This may include their duration of diagnosis and involves dietitians eliciting information about the previous advice patients have received and their understanding of their condition and their medication before proceeding.

> *"And a lot of times in your clinics you spend time answering questions that they've heard something or their daughter said to them something or their friend said to them something or they've read something. So, you spend a*

lot of time answering, trying to put everything into order and answering questions before you go to your main consult."

[London, Male, DSD]

RDs reported the need to first establish the patients' aims and to ground the counselling and advice within the context of the existing knowledge or understanding of each patient. There was a recognition that a health-related goal such as improving glycaemic control or losing weight might exist but that this may sometimes take the form of a hidden agenda on the part of the dietitian, and is not explicitly discussed with the patient, whilst addressing the initial concerns and goals of the patient themselves. There was very little discussion of patient goals outside of the medical model and dietitians did not mention if they took time to establish the patients' needs with regards to how they prefer work with the dietitian. There was a sense of RDs desire to help patients with T2DM and this was very much focussed on achieving targets for blood glucose and weight, as part of the medical model, which is likely driven by external factors such as funding sources and government initiatives, or the dietitian's original training.

Stigma and guilt are often associated with a diagnosis of a lifestyle-related condition such as type 2 diabetes.[186] Dietitians showed acute awareness of patients being made to feel as though they have done something wrong by other health professionals prior to seeing the dietitian. The importance of this was recognised for their first interactions with the patient, even suggesting the first appointment is therefore not about diet at all.

"…there's nothing more daunting is you've just been sent to see someone because you've been naughty, that's the perception they have."

[Birmingham, Female, DSD]

"I mean, an initial consultation for me, quite often, I just listen to a patient rant for ages, about every clinician they've seen… it is rapport building in the initial consultation, and then education."

[Birmingham, Female, non-DSD]

Conversely, dietitians in other focus groups highlighted the importance of patients understanding why they had developed T2DM, which may in turn engender patient feelings of guilt and stigma in relation to excess body weight, poor eating habits and a lack of physical activity.

The need to 'undo' the previous poor advice of other health professionals, friends or family was seen as an important yet frustrating task by dietitians. Dietitians referred to dispelling myths perpetuated by others as a task which must be completed before then addressing the patient's goals or the dietitians' goals of the consultations.

"…it not might be weight but for other people it might be spending the whole time exploring things they'd been told by others, so demystifying it all."

[London, Female, DSD]

"…it's actually readdressing some of the myths they've picked up. I can't eat grapes, or whatever it is, that kind of stuff. Or, I can't exercise without having a Mars bar first, and all that kind of stuff. I find that, depending when they've come to me, it's thinking about righting some of the

perceived wrongs, or the perceived rights, and then taking it forward from wherever they want to go."

[Birmingham, Female, DSD]

Theme 1 (a): Dietitians as professionals and disagreements about approaches

In two of the focus groups there was discussion about dietitians as professionals being either undervalued, criticised or misunderstood by other professions and the public. This was related to both the importance of diabetes and the dietitian's role within in, and a belief that dietitians have a unique set of skills with which they are able to support patients with diabetes. Dietitians expressed a protectionist view of diabetes education, suggesting that they believe are the only professional group qualified to both deliver and 'police' diabetes education and advice.

"…we can not have the local dustbin man, seriously, I'm not joking, the local dustbin man going to do a three month nutritional qualification and then thinking he can go and deliver bloody diabetes advice to patients. Because this is what's happening, this is what is happening, you can't belittle diabetes."

[London, Female, DSD]

"…like this national diabetes prevention programme, I think what should have been in the contract really is that there should be diabetes dietitians employed within that contract to make sure the people delivering these programmes are delivering the right messages. Because basically what they're doing is they've got any Tom, Dick and Harry who's got a little bit of a degree in nutrition going out there giving, sorry, crap messages and there's nobody to police that, there's nobody to police that."

[London, Female, DSD]

A difference was observed between specialist and non-specialist RDs as the specialists appeared to link their dissatisfaction with under-qualified workers taking roles dietitians should fulfil to the importance of high quality diabetes care. In contrast the non-specialists were more concerned with others' ill-informed views of dietitians and misconceptions about their role or how they practice.

"if you look on diabetes forums all they're saying is us dietitians are giving them hundreds and hundreds of grams of carbohydrate, and what you're saying is completely different. That's quite interesting."

[Cardiff, Female, non-DSD]

"But I think that's where we can look at things holistically...So I think that's the difference. We can look at it and pick out those things, the pitfalls. Whereas the likes of other experts, they don't see that do they? All they're looking at is the carbs."

[Cardiff, Female, non-DSD]

"…most doctors and so many other people think that dietitians are woolly because they see the plate model and they think it's dietitians who brought it about…"

[Cardiff, Female, non-DSD]

In discussions about patient case scenarios (Appendix 12), there were disagreements amongst the dietitians regarding the optimal approach in three of the four focus groups. In

one case it was the general approach that differed and in the other two the disagreement was regarding specific aspects of the advice.

"I would probably try and put the fear of god in him, to try and make him lose some weight. But, it would depend if he would take it or not."

[Birmingham, Female, non-DSD]

"I don't think I'd try and put the fear of god in him. But, I think I would definitely spend some time discussing the impact of, kind of, his weight on his glycaemic control."

[Birmingham, Female, DSD]

Whilst it would be unreasonable to expect all professionals from a certain discipline to agree precisely, it is notable that these individuals felt the need to challenge one another or to express a different view in the focus group, also demonstrated in the example below. This may reflect aspects of group dynamics as well as differences in understanding of the latest guidelines or the evidence base.

"That's why I always say three meals and two snacks just to avoid the big gaps in between."

[London, Female, non-DSD]

"But you don't need snacks with NovoMix 30, you just need to eat breakfast, lunch and dinner."

[London, Female, DSD]

Theme 2: The role & importance of carbohydrate in type 2 diabetes

Dietitians almost universally agreed that carbohydrate is an important consideration in the diets for people with T2DM, put succinctly by one participant.

"Well, I think it does influence blood glucose so, therefore, we should assess it and see how much and of what type."

[London, Female, DSD]

"If I have somebody brand new and they are very much like a blank sheet I would place emphasis on carbohydrate, and total carbohydrate, and start to distinguish between different types very early on, like initial appointment. It's the nutrient I would place the most priority on at the beginning."

[Cardiff, Male, DSD]

Exceptions to this occurred predominantly in RDs not specialising in diabetes, where they described a focus on calories or generic portion control for weight management, and even suggested that the topic of carbohydrate is not discussed at all in some cases.

"I probably think, when it comes to my intervention, I don't place a heavy focus on it. I work more on calorie reduction as a whole."

[Birmingham, Female, non-DSD]

"I guess for a lot of them as well it's just weight management and however they can cut back the calories, and if that works for them, then it's not the end of the world if they're slightly higher in carbs as long as they're cutting back on calories."

[Glasgow, Female, non-DSD]

One specialist RD explained that they may not discuss carbohydrate depending on the current pharmacological treatment of the patient.

"I don't discuss carbohydrate in every consultation, so for patients...for some people who come in, depending if they're on diet alone or diet plus Metformin, it might not come into the conversation, carbohydrate. I might more speak about weight management and just overall energy intake…"

[London, Female, DSD]

The way in which RDs described discussing carbohydrate with patients is less consistent, however, although 'Carbohydrate Awareness' was a phrase commonly used across the focus groups and the descriptions or definitions of carbohydrate awareness shared many common elements. Knowing what carbohydrate is, or which foods contain carbohydrate, understanding its varying effects on blood glucose and even having an understanding of suitable portion sizes were mentioned in RDs' descriptions of carbohydrate awareness advice currently given in all the focus groups.

"I think it is important that they understand what carbohydrate is, they understand what effect it has on their blood glucose levels, where it sits within weight management."

[Birmingham, Female, DSD]

"I think they have to understand, they have to be aware of it and to understand what the carbohydrate and what type of foods that contain it

and that gives them that bit more knowledge and understanding of the different types of food and to be aware of and go through how much I should be eating of it."

[London, Female, DSD]

There was disagreement between focus groups about how to differentiate between different types of carbohydrate, with some dietitians reluctantly using the terms 'good carbs' and 'bad carbs', whilst others described the importance of avoiding this dichotomous view, to help avoid patients seeing carbohydrate as 'evil' or something to be avoided.

"I hate to use the word good or bad carbs, but it's a simple way of explaining to people. But I think it's important that they distinguish the difference between if you have a sweet potato and a bag of sugar it's not the same thing."

[Cardiff, Female, non-DSD]

"I tried to calm down the patient and tell him that the carbohydrate is not an evil thing."

[London, Female, non-DSD]

There was also some frustration expressed with how carbohydrate is portrayed in the media, leading to negative public perceptions, and without considering the overall nutritional quality of carbohydrate-containing foods.

"And it seems to be the baddie just now, it seems to be that sugar and carbohydrate are bad for you, but it is…it's such an important food group because of all the B vitamins and fibre, and people just hear headlines."

[Glasgow, Female, non-DSD]

Theme 2 (a): Types of Carbohydrate Advice Given

Most RDs reported they avoid giving advice about specific quantities of carbohydrate but sometimes expressed amounts of carbohydrate either as a percentage of total energy intake, or vaguely as a part of overall calorie and portion reduction. In one focus group several participants made reference to nutritional guidelines that were out of date with respect to the amounts of carbohydrate recommended and expressed uncertainty at this part of the discussion.

> *"I'm not quite sure what the recommendations are now, percentage of your total energy, but I know…I sometimes think if it's…we're still going down that road, it's too high. We did go…at one time we went from much lower carbohydrate, it was about 40 per cent, and then we went to 60 per cent carbohydrate…"*

[Glasgow, Female, non-DSD]

In another group participants did refer to ranges of amounts of carbohydrate which they share with patients or groups of patients, something which other groups seemed reluctant to share.

> *"I'll talk about the 120 to 250 range, and I'll say, not knowing too much about everyone, you likely will all sit within this range. There may be one individual who will sit under and one of you maybe will sit over, however I think likely we're in that, and then I say some of you may be towards the*

lower end of the range, if you're not exact over or if you're watching your weight or if your levels are very high."

[Cardiff, Male, DSD]

Dietitians often talked about the difficulties associated with giving patients carbohydrate advice as part of the consultation.

Covert carbohydrate advice was mentioned in 3 out of the 4 focus groups, whereby the dietitians explained they are targeting either the amount of type of carbohydrate in the patients' diet, without overtly explaining this or their rationale to the patient. This implies there was a judgement made by the dietitian that there was no need to explain the basis for the advice, that it would not be understood by the patient, or perhaps there was a lack of clinical time to spend explaining their rationale.

"I think it's more with some of the patients I see it's a case of sometimes keeping it simple or just saying, okay, this rice portion you might be having what could we learn to replace it with? And then it's replacing with protein or more vegetables, for example. So, you're not really getting them too bogged down with the idea of it's carbs, it's carbs, it's carbs…"

[London, Male, DSD]

Theme 2 (b): Determinants of specific advice about carbohydrate

In all of the focus groups two types of factor featured heavily in determining how dietitians advise patients about carbohydrate. Diabetes medication or social, cultural, family and ethnic factors were strong drivers of how dietitians reported they approach different patients.

"I think that if the patient is on a medication that actually lowers blood glucose irrespective of their current glucose and, for example, if they're on insulin or they're on Gliclazide it is very important they understand the effects of carbohydrate and then explaining about poor...even approximate portions."

[London, Female, DSD]

The effects of medication for lowering blood glucose changed the emphasis towards ensuring there is sufficient and regular carbohydrate to avoid hypoglycaemia, which may become an area of conflict and confusion for people with diabetes.

"We don't give any advice per se on, eat 50 grams at x time of day, or anything like that. We will put different emphasis on it, depending on the medications there are. So, if they're insulin treated, and they're on mixed insulins or fixed doses, we will talk a lot more about consistency of carbohydrate portions."

[Birmingham, Female, DSD]

Culture or ethnicity may lead the dietitian to focus on stereotypical sources of excess carbohydrate in the diet. This also represents a potential conflict with RDs' stated aims, which often cited the patient's goals as a driving force. Patient ethnicity in particular appeared to be a precursor to dietitians resorting to stereotypes and generalising how patients may need to be advised regarding their diet.

"…the patient group that I was specifically working with, like the ethnic groups and stuff, the carbohydrate was such a big part of their diet. So in

terms of the rice, things like paratha and lots of carbs, carbohydrate was significant even if it was weight management, often even with the weight management it was a case of, okay, so let's look at your carbohydrate portions and let's look to see what they are and let's maybe look to reduce that. So actually, that often would be a common theme with certain patient ethnic groups, for example."

[London, Male, DSD]

It was evident from the focus group discussions that diabetes medication is the strongest driver for how dietitians approach their advice about carbohydrate, with some relating this to safety aspects and the avoidance of low blood glucose or hypoglycaemia; which can only occur as a result of diabetes medications.

Other, less frequently noted factors, include the influence of duration of diabetes diagnosis, their literacy and numeracy levels, and the patient's blood glucose control.

To a much lesser extent, some of the focus group participants did focus on the individual variation in patient needs or their preference and aims when determining how to focus their advice.

"I think, ultimately, to achieve anything for our job, it has to, kind of, be patient led, and it's then taking responsibilities for their health…. Are they in that moment in time where they can make a change? That's what I mean by that, kind of, centred approach."

[Birmingham, Female, non-DSD]

Theme 2 (c): The meaning of carbohydrate awareness for dietitians

The use of the word carbohydrate with patients amongst focus group participants and the meaning of the term 'carbohydrate awareness' varied to some extent but there were some very strong recurring themes. In terms of defining carbohydrate awareness, there was general agreement that it should start with people being able to identify foods that contain carbohydrate and which foods may impact on blood glucose.

They [people with diabetes] need to be able to identify what foods contain carbohydrate. Basic.

[Cardiff Female, non-DSD]

"Making sure somebody knows which foods…well, in layman's terms, which foods are going to have an impact on blood sugar level and which are going to have no impact at all."

[Glasgow, Female, non-DSD]

Opinions then diverged in the degree of emphasis dietitians place on the topic, whether the definition should include discussing portions or specific quantities, or the subject of types of carbohydrate foods, for example high or low fibre or glycaemic index. However, at its most simple level, it was felt that identifying carbohydrates is the foundation of carbohydrate awareness, with the addition that more carbohydrate will lead to greater increases in blood glucose.

"So, what is a carbohydrate, different sorts of carbohydrate, and the amount of carbohydrate, and just a simple message that, the more carbohydrate you eat, the more glucose will get into your body. And, those

three things, I think, for me, that's what carbohydrate awareness is for me."

[Birmingham, Female, DSD]

There were differing views on the degree of emphasis that should be placed on 'types' of carbohydrate. This typically referred to either the glycaemic index of the fibre content of carbohydrate-containing foods.

"It is, it's just being aware of the types of the carbohydrate and the effect it has on your blood glucose level, the more you have the higher it's going to be."

[London Female, DSD]

"I think for carbohydrate awareness for me, is educating. So, what carbohydrate is, what it is, the types of carbohydrate, whether it's high fibre, low fibre, or use the GI word, if we think it's suitable."

[Birmingham, Female DSD]

Some participants felt the focus of carbohydrate awareness should be placed on the speed at which different carbohydrate foods affect blood glucose, also known as the glycaemic index.

"I think carbohydrate awareness is the difference between the rapid acting carbohydrates and the slow acting carbohydrate and focusing on that as well as portion size."

[Glasgow Female, DSD]

Other RDs felt it was important to contextualise carbohydrates within a modern diet and attempt to focus the message on sources of carbohydrate that are helpful or less helpful.

"I tried, initially I tried to calm down the patient and tell him that the carbohydrate is not an evil thing, but then I give them a history of like the western society tend to eat quite a lot of refined carbohydrates."

[London, Female, non-DSD]

4.3.2 Summary of Round One of RD Focus Groups

RDs rated highly the importance of addressing the patient's aims, individualisation of care, and taking account of the patient's culture and previous knowledge. There was general agreement of the importance of discussing carbohydrate, although some RDs reported not using the word 'carbohydrate'. The determinants of the sort of carbohydrate advice patients receive, as reported by the RDs in the focus groups, were not primarily focussed on what the patient has expressed or identified as their personal needs. There was some agreement on the meaning of carbohydrate awareness but increasing divergence the further the explanation was developed by each dietitian.

A dissonance is emerging between aspects of what dietitians reported as their approach and what was found in the patient interviews, since aspects highlighted in the analysis of the patient interviews suggest dietitians are failing to meet the expectations of patients. The conflict appears to be in the route taken to achieve the goal or aim, rather than necessarily failing to share a common goal between the patient and the dietitian. In other words, the educational or therapeutic methods deployed by the dietitian, their style or general approach

may be the issue which patients interviewed are reflecting on but did not vocalise in the same manner.

Contradictions between what dietitians say they do, or is important to them, and what patients say they experience (individualisation, taking account of culture, previous knowledge etc.) are likely to be heavily influenced by the ability to recollect (patients), self-perception (RDs), and pre-conceived ideas or expectations regarding the role of a Dietitian (patients). It suggests RDs may benefit from paying particular attention to patient expectations and perceptions as part of their assessment and regularly reflecting to the patient throughout the episode of care how they are tailoring they approach to this.

4.3.4 Round Two Focus Groups

The aim of the second round of focus groups was to explore and understand what RDs think should be done to improve the way people with T2D are advised regarding carbohydrate.

Despite clear direction to the topic, discussions in focus groups continued to centre on how dietitians currently practice, with the frequent use of anecdotes to illustrate their current approaches to carbohydrate advice in T2DM. Therefore, some repetition with the first round of focus groups was observed. Four overarching themes and sub-themes within some of these were developed though thematic analysis. Main themes were common to all four locations and, as with all qualitative thematic analysis, there is some overlap between themes and sub-themes, which are outlined in **Table 11**.

Table 11 – List of themes and sub-themes for round two RD focus groups

Main Theme		Sub-theme		LON	BIRM	CARD	GLAS
1	Guidelines & Individualisation	1a	Challenges & Barriers	•	•	•	•
		1b	Patient-centred	•		•	•
		1c	Standardisation & Language	•	•		•
2	Differences between RDs			•	•	•	•
3	Changing the practice of RDs			•	•	•	•
4	How to educate patients	4a	Resources	•	•	•	•
		4b	Technology	•			•
		4c	Patient Reflection	•			•

Theme 1: Guidelines & Individualisation

A core element to individualising advice for RDs was the assessment of both the patient's current diet and of their knowledge of carbohydrate and diabetes, as well as their treatment, with less focus placed on establishing the patient's wishes or preferences as part of the process of individualisation. RDs referred to the importance of the agenda being patient-led but typically this was with respect to the knowledge patients would like to acquire, 'what they would like to know', and did not go as far as establishing other wishes or preferences. The concept of individualisation is one of targeting the advice based on the RDs determination of what knowledge is required, rather than what ascertaining what the patient wants or needs. Some RDs acknowledge this is not undertaken satisfactorily with each patient. In fact, one focus group highlighted specific cultural factors which would lead them to purposely avoid tailoring their approach to be patient-led, citing one cultural group as an example where they felt it was poorly received and instead a directive approach should be adopted instead.

"So, to ask them what they want to know first before we go off on our own agenda. Sometimes they don't want to know all the foods that have carbohydrates and portion sizes."

[London, Female, DSD]

"And it's being quite didactic. With the Arabic population you have to be like that. If you're all nice and woolly and British they won't…"

[London, Male, DSD]

However, RDs universally desired clear guidelines regarding how to advise people with T2DM about carbohydrate, specifically requesting in some cases a formulaic approach using a calculated requirement, as is used in other areas of dietetics such as for calculating energy requirements. This highlights the difficulties and challenges RDs face in making therapeutic decisions in the absence of strong or clear evidence regarding quantities of carbohydrate and leads to an expressed conflict between their acute awareness of the need to individualise, against their wish for something more standardised. One focus group began to discuss the elements of the formula that would need to be incorporated before then realising it would be unlikely to be appropriate.

"So, I'd love to see some more guidance… Nutrition support, we've got all those lovely algorithms to use and there are guidelines, this is how much protein, this is how much fluid based on…we don't have that for diabetes."

[Cardiff, Female, non-DSD]

"I think we need something like the Schofield Equation for diabetes."

[Cardiff, Male, DSD]

One focus group expressed a desire for lesson plans as part of a guideline to support the delivery of consistent messages for each patient, similar to those that are used in patient group education programmes.

"I think a lesson plan almost, so there's consistency across the board, because I think it's easy to have differences from even within the same health board…I think if we had like a wee lesson plan in place, then you could make sure that you're covering the topics in an order that you're meant to, or some sort of format. If there was a decided way that you're delivering or trying to get across points about carbohydrate or visual things or…agreed on, I don't know."

[Glasgow, Female, DSD]

Where there was general agreement there was also overlap with the views expressed in round one of the focus groups, regarding the definitions of terms and the types of language and explanations RDs suggest should be used.

Theme 1 (a): Patient-centred

Dietitians across all the focus groups demonstrated a recognition of the need for patient-centred care, often stating that the patient's wishes should be the starting point for their interventions. As part of this some dietitians referred to the importance of using behaviour change techniques and taking a realistic approach to the degree of dietary change possible.

"I say just start at the baseline, just go from there, because the average question they're asking is what can I eat."

[London, Female, DSD]

"What they want to get out of the consultation in the first place."

[London, Female, non-DSD]

"Because one of the first things you find out is what do you want to do? What do you want to look at?"

[Cardiff, Female, non-DSD]

Theme 1 (b): Standardisation & Language

There was discussion across three of the focus groups about the importance of using common terminology or explaining concepts to patients in the same way, with RDs suggesting it can be unhelpful for patients to receive different explanations from different dietitians, or varying amounts and quality of information.

"They should be at least given the same amount of information, the same quality and something with a structure so that everything is covered in a certain way. That it's not some people get a little bit of advice; some people get loads and then there's all this miscommunication in the middle."

[Cardiff, Male, DSD]

"I definitely think we all need to be saying the same words so that it makes sense for everybody. Definitely. I think that's something that's fundamentally wrong, 'cause people say just totally different things."

[Birmingham, Female, DSD]

This is in potential conflict with the need to individualise as described earlier, where dietitians described targeting the information patients 'need' to their current level of understanding and their expressed wishes for knowledge. Use of the word 'carbohydrate' was seen as important as part of standardising the terms used as it is a clinically accurate term that requires explanation, despite concerns that it may represent use of jargon or technical language.

"So I use that word carbohydrate to let them know it's starchy and sugary foods and not just sugary foods."

[London, Female, DSD]

"Cause I know that at, you know, I always remember at uni people saying, don't baffle them with technical jargon. But I think sometimes you have to be clinically accurate, and actually carbohydrate is the term"

[Birmingham, Female, DSD]

Theme 1 (c): Challenges and Barriers

All four focus groups recognised a wide range of challenges and barriers in relation to carbohydrate advice, ranging from the practical difficulties of educating patients with

different needs, to the potential for conflict between standardisation and individualisation, and overcoming communication barriers regarding the use of scientific language.

> *"…sound quite childish, but I think it's… I think sometimes with adults you have to physically see it to understand what you're… 'Cause I know we're talking about building blocks and all sorts, but I think sometimes for a lot of adults, the minute you start talking science they just switch off, you know. Particularly if you bring numbers into it."*

[Birmingham, Female, DSD]

RDs were concerned to pitch the information at the right level for patients and to do so in a practical way, perhaps using plastic food models or other props that help patients to understand, but without patronising patients or giving them information that is too scientific.

> *"I think using food models as well to help demonstrate portion sizes can be helpful, but I think some people find that a bit patronising as well, don't they, because it's like a childhood toy, but if food models are useful…"*

[Glasgow, Female, non-DSD]

There was a conflict with this belief in the Cardiff group, where over-simplifying of information was considered at risk of alienating patients.

> *"Because I think some of the…if it's seen as a very basic thing you'll get the wrong information coming out and patients will go away thinking that's a waste of space."*

[Cardiff, Female, non-DSD]

The concepts of individualisation and standardisation were viewed by RDs as mutually exclusive and incompatible, or at least they were concerned they may risk being accused of using a 'one size fits all' approach to advising patients. There was a lack of recognition of how care can be individualised whilst still following a guideline or some standards of best practice. RDs in the focus groups expressed views of standardisation involves providing all patients with the same information in the same way.

> *"…it's so hard though because then equally you say well, yeah, you can have this, but then you're trying to make it so individualised, and then you're factoring but maybe do you need to be a bit more didactic. So, I didn't ever come up with an answer. I just decided this is always going to be very challenging."*

[London, Male, non-DSD]

> *"Then the counterargument to that is always this whole notion of if you then introduce something universal you then get the finger pointed of it's not individual then, why is it not individually tailored. So, it's kind of this ongoing tension between following guidelines, being universal versus oh, we're being patient led and centred and individual tailored plans."*

[Cardiff, Male, DSD]

Communication barriers, the risk of misinformation from the choice of language or the confusion that can arise from information provided by other professionals were all seen as challenges by RDs. One concern was that reliance on visual information to overcome language barriers can lead to misinterpretation of the intended message and subsequently to patients not following the correct advice.

"One of the problems, you know when people don't speak English and you use a visual aid like the Eat Well guide, that can really give the wrong message because it doesn't show the portions and they just think I've got to eat a lot and they always fill themselves with starchy foods."

[London, Female, DSD]

In another focus group the impact of information coming from other sources and diluting the message from the dietitian was highlighted, suggesting that either the alternative information is incorrect, or that it simply fails to reinforce what the dietitian has said.

"…information that they get from dietitians is getting lost with the clam of information they get out there. The doctor is telling them one thing, the practice nurse is telling them one thing, the media is telling them something else, and it's how information gets lost."

[Cardiff, Female, DSD]

Theme 2: Differences between RDs

There was discussion across all the focus groups about how dietitians may differ in their approaches, and some disagreement within the groups amongst the RDs present. The background or training of the dietitian were cited as possible factors influencing differences in practice, and there were questions about whether all RDs seeing patients with diabetes need to be specialist RDs with a minimum number of years of experience.

"I think we're all just being very individual with how we advise the patient, just really trying to tune into that patient. So, what I think I'm trying to

propose is actually you have to have a minimum number of years before you can go and see a patient and start advising on diabetes."

[London, Female, DSD]

Some of the challenges and differences highlighted between RDs' background related to the diversity of populations and whether they have the cultural understanding required.

"I think sometimes you may get dietitians coming from a certain country like Australia where it is all white people. We living in London are used to working with different cultures, and I think sometimes you might get the Australia dietitians, for example, just saying nonsense to the patients, to be honest, to be a bit blunt."

[London, Male, DSD]

This links to the earlier theme regarding individualisation and guidelines, whereby RDs wanted clear guidelines but recognise the difficulty of maintaining consistency and yet individualising care.

"I definitely think we all need to be saying the same words so that it makes sense for everybody. Definitely. I think that's something that's fundamentally wrong, 'cause people say just totally different things."

[Birmingham, Female, DSD]

The way it was discussed as part of this theme suggests RDs in this study feel this level of skill demands a certain degree of expertise or experience that is absent in newly-qualified

dietitians. These views were expressed primarily by specialist dietitians with many years of experience and, although the focus groups in which this was mentioned included dietitians that were non-specialists, there was general agreement within the groups and nobody challenged or disagreed.

"I wonder as well coming back to the question and like the research you've found out so far is having a specialist dietitian doing it, or at least someone really trained in carb counting rather than just a general band five doing general clinic."

[Cardiff, Female, DSD]

Theme 3: Changing professional practice of Dietitians

Several areas were felt to be important for changing how RDs practice, including student training, continuous professional development (post-registration training) and the value of observation post-registration. There are questions from experienced dietitians regarding the contents of student training and the value attributed to diabetes as part of their training programme.

"I don't know what students have been taught exactly with that these days, but student training is, they just sort of zip through diabetes as well, they don't really get a week or two weeks unless it's sort of their consolidation ward… I had carbohydrate exchanges drummed into me as a student, that's a long time ago, and I think we've come away from that a wee bit, and I think we need to know about that."

[Glasgow, Female, non-DSD]

"Are they taught carbohydrate counting during their training? I think I certainly was and we did a lot on food weighing and portion control. I don't know if students are doing that now."

[Cardiff, Female, DSD]

This suggests the RDs felt student dietitians have little motivation to develop their diabetes knowledge to the required level and end up focussing on other, rather basic, aspects of the dietetic care of people with T2DM. There was uncertainty amongst the dietitians about what students are taught with regards to diabetes and carbohydrate and frustration that students don't come into practice placements with a focus on carbohydrate.

"I think the students come in with…nutrition support is really what they think the bulk of their work is, and the bulk of their training is… and when they're doing diet histories at the start, but get them to focus on the carbohydrates, and they're just measuring the protein, checking if they're having full cream milk. No, it's the carbohydrates you want. The number of times I hear them ask what type of milk, it makes no difference in diabetes. It makes a slight difference in the weight, unless they're drinking pints and pints of it, I don't care what milk they're drinking."

[Glasgow, Female, DSD]

Continuous professional development (CPD) or training for post-registration dietitians was mentioned across three of the focus groups. This referred to training for those that are already specialist or experienced but also so that there is a minimum standard of training for all dietitians working with carbohydrate advice in T2DM. This suggests that the dietitians recognised there are skills necessary that not all dietitians can be expected to possess, but

which are necessary in order to improve dietetic practice in this field. There was also a recognition that the skills are more than diabetes-specific and also relate to the consultation skills in working effectively with patients.

"I think as well it's making sure you keep up to date with CPD, if you're not doing diabetes all the time, moving with emerging evidence instead of being stuck in the one place, advice from the eighties."

[Glasgow, Female, DSD]

"I would like to see a form of carb counting training to be introduced, both for dietitians and then to be cascaded to patients. At least again the option of."

[Cardiff, Male, DSD]

The dietitians also recognised the value of other, related skills. For example, consultation, counselling or behaviour change skills besides simply knowing about carbohydrate.

"I completely agree, like you're saying, having some post graduate training, but actually incorporating a component that is about patient interviewing, because I think that's coming across like a key thing, that patients want to be understood, so actually having some post grad training to then go into the diabetes space I would completely agree with."

[London, Male, DSD]

Theme 4: How patients are educated

Discussions regarding methods of educating patients focussed heavily on resources and RDs expressed a wish across all groups for some standardised, even national, written or printed resources.

> *"So we need almost like a standardised visual aid that actually dietitians could use kind of UK-wide to be able to explain it. And that could, again, essentially, form kind of part of a guideline, couldn't it, on how to go about kind of explaining it to make sure it is standard."*

[Birmingham, Female, non-DSD]

Predominantly there was a desire for the published resources to be visual in nature, and many focus group participants referred to existing resources as examples of good practice, such as the 'Carbs and Cals' range of books.[187] The concept of the resources was centred around 'show not tell' so it was felt important there are either images or food models available to dietitians in educating patients.

> *"So if you can show a portion size, because I think it's kind of tricky sometimes, so if you can just show a portion with this and then you might say are just having a reduced amount, or if you're not showing them and you're just kind of talking about it their idea of what they think is a reduced amount is completely different from what we think until you actually show them."*

[London, Female, DSD]

"Just something really simple even if it's just like a picture. Because in most other things you've got the Eatwell Plate or the Eatwell Guide now and there's so much going on in that."

[Birmingham, Female, non-DSD]

Theme 4 (a): Patient Reflection

An important aspect of educating patients was drawing on the patient's own experience and supporting them to learn through discovery and reflection, highlighting the value of this previous experience and helping patients to develop insight into their own behaviours and where dietary change may be possible.

"So even before we even give advice it's try to make them aware of what their current diet's like so that you can talk about changes to it so they're actually aware and say I didn't realise but I actually eat a whole bag of chocolates watching telly and I didn't even know, I thought I was only doing it once a week when actually I do it five times a week."

[London, Female, non-DSD]

This may be useful for RDs as a way of fostering autonomy in their patients rather than creating dependence by taking a directive, didactic approach. Focussing on developing skills as well as offering advice and information is an aspect of dietetic care in diabetes that was not discussed in all the focus groups but where it was there was a general agreement within the group.

"It's encouraging reflection for the patients, so that can be effective sometimes, so even from that alone, you can tell the patient where you've

obviously not got enough insulin for what you're eating earlier on, too much carbohydrate earlier on, that kind of thing…"

[Glasgow, Female, DSD]

Theme 4 (b): Technology

The use of applications or 'apps' in the dietetic care of patients with T2DM was raised in one group where it could be used to both support the assessment and improve patient access to advice.

"I think technology's such a big thing, if we're a bit more forward thinking…everybody's got a smartphone these days, most of our patients do, if we could link in and use some sort of app or website that could consistently give us the same advice, it would be quite useful, but how you do that and how you get through this kind of whole governance to do that, I'm not sure."

[Glasgow, Female, non-DSD]

Despite their enthusiasm for the use of technology in this way, there was a general sense of uncertainty around how to access or implement it, and even in terms of what is currently available. This may represent a future development need for dietitians, given that they recognise the prevalence and potential value of apps, but lack the skills or knowledge around their availability and use in the healthcare setting. The quote below highlights a lack of awareness that apps are currently available which meet this expressed need.

"If there was something that patients could bring with them, almost like an app that they recorded their activity, that they point…kind of they were

to pick portion sizes of what they had, so that when they came to you, you had an idea of actually what their lifestyle is."

[Glasgow, Female, non-DSD]

Dietitians also valued web sites as a resource for themselves and for directing patients to, although some uncertainty continued with regards to what is available or where to find reliable content, such as videos.

"Yeah, I suppose that we're very techy these days and I think that's quite… I don't know if that's quite a young thing? I don't know if that's a horrible thing to say 'cause my mum uses a smartphone and all the rest of it. But, you know, you've got video clips and YouTube and I don't know if there's any way to… 'Cause there used to be a really nice video on…was it the DUK website?"

[Birmingham, Female, DSD]

There was also an acknowledgement that the use of web sites or online sources of information for patients may be more suited to a younger generation of patient, which suggests dietitians may be prejudiced in the type of patient who receives this advice. Some dietitians had specific knowledge of which web sites included reliable information and which that their patients would require further guidance to navigate effectively.

"It's actually pointing them to the right websites for example. So like I say to people diabetes UK, this is the one you look at and that's on their little diet sheet. Diabetes.co.uk, I said don't be…it's not regulated. Don't be put off by the comments. Some of the stuff is good."

[Cardiff, Female, non-DSD]

4.3.4 Summary of Round Two RD Focus Groups

The aim of the second round of focus groups was to explore what dietitians felt could be done to improve how patients with T2DM are advised regarding carbohydrate. The discussions continued to centre on the current practice of RDs, with less focus on how they might formulate an improved form of carbohydrate advice. It was also noted that there was a focus on the difficulties RDs face in advising patients with T2DM about carbohydrate, which linked the themes of the round two focus groups together.

The dietitians remained conflicted and somewhat uncertain to what extent they can balance their desire for clear guidelines that standardise their approach, against how to make sure patient care is individualised. Indeed, there is a sense that the two are antagonistic to one another which seems rooted in the dietitians' perception that individualised, person-centred care means providing information and education that the patient needs as determined by the dietitian's assessment, rather than tailoring their approach to the expressed wishes of the patients. The establishment of patient preferences of wishes appears to be a single time event that occurs in the initial assessment, as RDs did not describe referring back to this and re-checking the patient is meeting their own goals. There was much greater emphasis placed on establishing patients' aims and goals in the round one focus groups, which was not evidence in round two.

Dietitians felt changes to the training of student dietitians, as well as post-registration training had a role to play in improving dietetic practice to support improved carbohydrate advice to

people with T2DM, but there was a suggestion that dietetics in diabetes deserves more recognition as a specialist role even at what has been previously considered the 'basic' end of the spectrum with regards to patient complexity.

The resources dietitians use in educating and supporting patients with T2DM were considered an important part of the advice, so much so they were sometimes discussed as the basis for how patients are advised. There was a recognition that it is preferable to 'show not tell' with the use of printed pictorial or other resources, but some reservations about the potential to patronise or over-simplify the message by use of childish educational tools such as food models.

4.4 Overall Summary of Patient Interviews & RD Focus Groups

The analysis of the patient interviews found that people with T2DM generally positively regard and report a favourable experience after receiving advice from a dietitian regarding carbohydrate. Patients appreciated being listened to and reassured by their dietitian, as well as having advice that was clear ('what to eat' / 'what not to eat') and tailored to their social and cultural circumstances. The desire for advice that is made practical and individualised to each patient was a strong theme in across the patient analysis. Unsurprisingly, patients were less satisfied if they felt the dietitian was patronising or not tailoring the information to their needs, demonstrated a lack of awareness or understanding of their culture or was repetitive with a lack of continuity through seeing several different dietitians.

The contrast between the analysis of the patient interviews and the focus groups centred on the many areas of overlap with regards to what dietitians say they do, or is an important part

of their practice, and what patients reported was lacking from their dietetic consultations. Dietitians talked about the importance of establishing the patient's aims, their existing knowledge or understanding of diabetes and diet, and of making sure their approach is person-centred and individualised. This incongruity suggests that dietitians lack insight into their skills in this respect or that the patient is poorly able to recollect the consultation. This dissonance is a significant finding that will ultimately have influence over how dietitians can improve their practice. Whether it is an issue of recollection or perception on the part of the patient, the dietitian has an opportunity to bolster this aspect of their consultation skills in order to affect a positive outcome on the patient's experience. The principal aim of this study was to inform the development of a new form of advice for carbohydrate in T2DM and, whilst this aspect of practice development in consultation skills does not specifically relate to the details of carbohydrate advice, it appears to be an important factor that can influence patient experience.

With regards to the specific advice that dietitians think should be provided, there was some consistency of opinion of the defining aspects of 'carbohydrate awareness advice' but there was also divergence of views. Dietitians generally agreed that the explanations provided to patients should include how to identify carbohydrate foods; understanding that carbohydrate is the principal nutrient affecting blood glucose and these foods will cause blood glucose to increase most; and some concept of portion size, or that larger portions will result in greater increases in blood glucose. Where opinion diverged was the subject of glycaemic index and fibre, or in other words the type and quality of carbohydrate rather than the quantity. Several focus group participants across all groups felt strongly that carbohydrate quality ought to be included in carbohydrate awareness advice, but also recognised it added a level of complexity

to the advice and as such some dietitians would only include this advice in a covert manner, by promoting the relevant foods but without using the terminology or explaining the rationale to patients.

CHAPTER FIVE

APPLICATION OF KLEINMAN'S THEORETICAL MODEL

5.1 Introduction

This chapter will discuss and apply a theoretical model to the results presented in **Chapter Four**, in order to add a further layer of interpretation to the findings using Kleinman's Explanatory Models in health care and the associated concepts.[35] Reeves [188] describes how theories are used in qualitative research as a 'conceptual tool useful in making sense of a complex social reality' and how they help researchers to gain new insights into their data and analyses. In **Chapter One** the complex nature of food choices and managing a long-term condition such as T2DM were both outlined, along with a brief introduction to some of the key concepts within Kleinman's Explanatory Model.[81] This chapter will ultimately lead on to present the development and description of the Carbohydrate Awareness Advice Framework (CAAF).

Theories in qualitative research can be applied either at a conceptual or operational level and are often entangled with the methods used, in fact even the theories themselves are sometimes referred to as 'methodologies' making the method and theory implicit, however the theory itself may not even be fully visible as part of the reported research.[189] This can make the use and application of theories both challenging and potentially confusing to the novice researcher. In an attempt to improve the clarity and visibility of the theory applied in this thesis, this Chapter uses a conceptual theory in a partially retrospective manner, which corresponds with the typologies proposed by Bradbury-Jones *et al* [189] at Level 4 (of 5 levels) of 'theoretical visibility' in research. This means the theoretical model was applied to the data

after the initial model-free thematic analysis presented in **Chapter Four**. The purpose of applying a theoretical model to the qualitative data presented in the earlier Chapter is to bring together the findings and analysis from the patient and dietitian data in a way which offers additional meaning and insights beyond that which could be obtained from model-free thematic analysis alone. Kelly [150] suggests that 'generic' qualitative research using model-free theoretical analysis methods may struggle to go beyond merely describing the data. Theoretical models can also be used as an 'organising framework' in which to structure data or findings. Whilst Kleinman's [81] theory did not directly influence the initial development of the research questions and objectives of this thesis, it became clear through the first analysis of the data that a theoretical model would be of benefit to enhance the interpretation and application of the findings, and in particular in answering question three, which requires the bringing together of all the findings. In this sense it is being used as more than simply an organising framework. In fact, Kleinman's model was chosen for its potential to explain the apparent disconnect between the two data sources, which could help to inform the development of the framework for carbohydrate awareness advice. Therefore, this Chapter aims to demonstrate the highly applicable nature of the chosen theory to the data and to the overall aims of the research, which will be achieved through the use of excerpts to support the narrative throughout the Chapter. Whilst some attention was given to the methods used in relation to the application of a theoretical model in **Chapter Three**, further explanation is provided here.

5.2 The application of Kleinman's Explanatory Model & Concepts to the data

As already outlined, Kleinman's [35] explanatory model and associated concepts were applied to the data after the initial analysis stage. As part of formulating the themes and interpreting

the meaning underlying the text, it was possible to begin to identify how the data could be mapped to the social arenas and other concepts described by Kleinman. The process was conducted in the following chronological order:

1. Coding of transcripts for patient interviews using model-free thematic analysis methodology.[106]
2. Development of themes for patient interviews.
3. Coding of transcripts for RD focus groups using model-free thematic analysis methodology.[106]
4. Development of themes for RD focus groups.

   [See **Chapter Three** for further details describing steps 1-4]
5. Review of patient interview data and RD focus group data simultaneously to identify aspects which map to Kleinman's theories (described later), namely:
   a. Explanatory models.
   b. Three social arenas (popular, folk, professional).
   c. Culturally adaptive tasks (e.g. meaningful explanations, labelling & classifying, cultural healing).
   d. Concepts of illness vs. disease.
6. Code sections of data (interview & focus group manuscripts) which reflect or contain examples of text which reflect any of the four chosen elements of Kleinman's model above (a-d).
7. Using selected quotations from the data to illustrate, describe each of the concepts listed above as themes, alongside a narrative to support the application of the theory.

8. Discuss how this analysis offers additional an interpretation of the findings, beyond the model-free thematic analysis, which can then inform the development of the carbohydrate awareness advice framework.

5.3 Kleinman's Explanatory Model & Concepts of Healthcare – An Overview

In 1978 Arthur Kleinman developed a model that was intended to be capable of comparing 'medical systems as cultural systems' in order to 'understand health, illness and healing in society as cultural systems'.[81] This means that in order to understand and improve health and health care systems it is necessary to go beyond the biomedical model of disease, which despite being responsible for immense advances in medical care and life expectancy, is concerned with 'discovering the pathology rather than understanding the illness'.[190] A psychiatrist by background, Kleinman applied his learning from social and cultural studies of illness in Chinese and East Asian populations to develop the model and associated concepts and makes the case that 'medical systems are *both* social & cultural systems'.[81] This model remains relevant today and is able to provide additional meaning to qualitative analysis in applied health research, as will be argued in this Chapter.

The key focus of Kleinman's work on describing and developing the model is on culture, which he defined as 'a system of symbolic meanings that shapes both societal reality and personal experience'.[81] It is that focus of the framework that lends itself so aptly to the findings of qualitative work regarding the experience of people with diabetes who have received advice from dietitians. Similarly, it can also be applied to explain what dietitians collectively report they are doing with their advice and how they think it could be improved. Kleinman [81] argues that the parts of healthcare systems mirror other cultural, symbolic systems and that this allows us to frame our understanding by means of how health, illness and health care relate

to one another. This is a useful starting point for explaining the discourse presented in **Chapter Four**.

Describing the elements of Kleinman's models and concepts which are relevant to the data obtained in this thesis, in a logical order, is challenging because there is so much overlap between them with regards to the underlying concepts. **Figure 8** is adapted from Kleinman's model of the health care system and incorporates the concepts which have been drawn upon to add an additional layer of interpretation to the findings presented **Chapter Four**. It has been designed to illustrate the overarching concept Explanatory Models, the underlying social and cultural tasks and concepts, and the core concept of the health care system with its popular, professional and folk domains. Clinical realities are also derived from many of these elements. Each of these elements from Kleinman's model and concepts will be described and addressed in relation to the data obtained in **Chapter Four**. Some overlap is to be expected as several of the concepts are related or co-dependent.

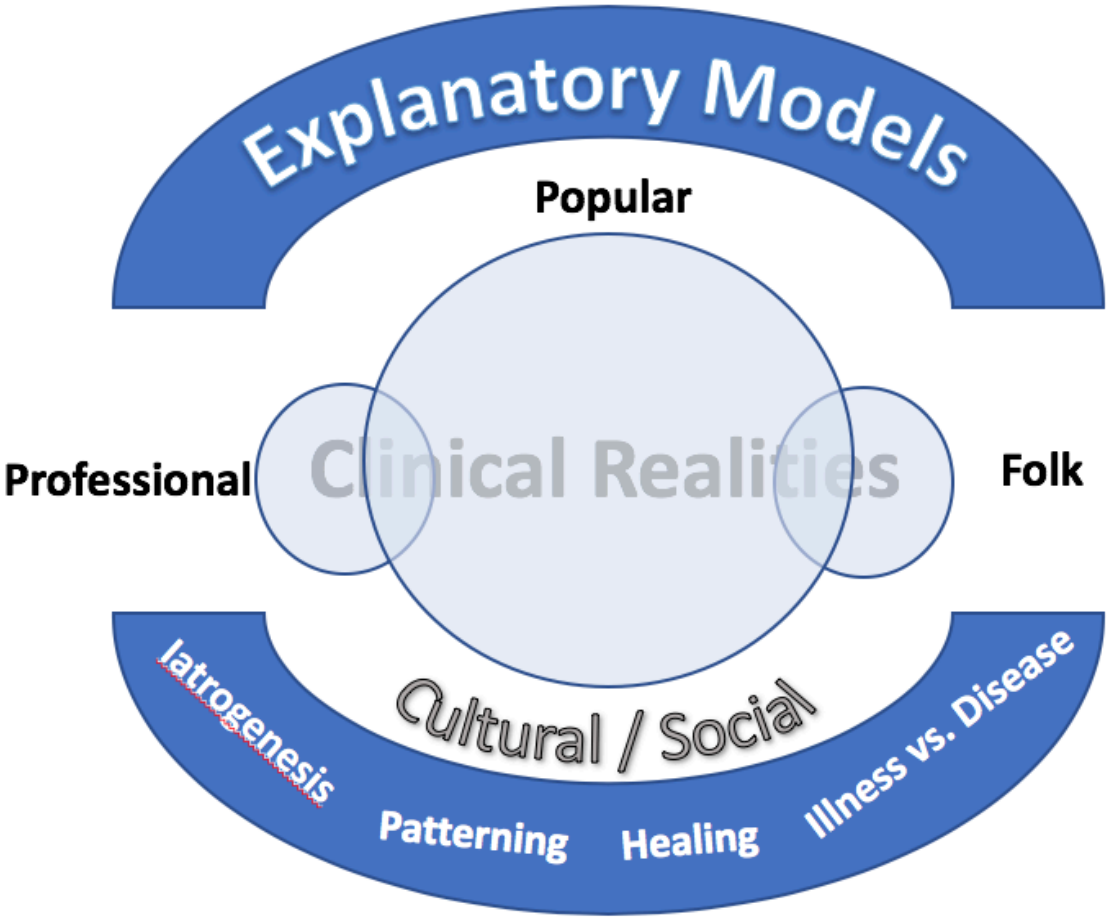


Figure 8 – Kleinman models and concepts (adapted from Kleinman[35])

5.4 Explanatory Models

Explanatory Models (EMs) can be most simply described a set of explanations for the development of disease, its onset and origins and how it is treated. These explanations are held by both patients and health professionals and may not be related to any biomedical basis of understanding, but can be rooted in the history, culture, beliefs and values of an individual or social group such as the family. Kleinman [81] describes a tension between the conflicting EMs of patients and professionals that may lead to poor care or dissatisfaction with care and, due to the social and cultural nature of EMs, means that resolving these conflicts requires health professionals to be competent in understanding the cultural basis of patients' EMs.

This 'cultural competence' [191] is seen as an important aspect of health professionals moving beyond the biomedical model of health care and working effectively within a system that is both social and cultural. Understanding differences in EMs and being able to communicate with patients effectively on the basis of those differences may then address the expectation gap between patients and health professionals and help health professionals understand reasons for 'non-compliance with health advice.

One patient talked about their strong personal and family history of diabetes and how this had a significant influence on their knowledge and understanding of living with the condition, suggesting that this experience had an important role in shaping their own EM. This particular patient expressed dissatisfaction with their care from the RD at other points in the interview and perhaps there was some conflict between the EM of the patient and the RD which was not fully explored.

"I mean, as I said, having been diabetic for 20 plus years, having looked after my mother. Diabetes in our family is rife. So having knowledge of living with diabetes, that primarily affected my…"

[P06]

In the RD focus groups, there was some talk of what could now be labelled 'exploring the patient EM' whereby RDs talked about demystifying previous advice patients had received or spending time helping patients to better understand their condition (see also 'Cultural Healing').

"…it might not be weight but for other people it might be spending the whole time exploring things they'd been told by others, so demystifying it all."

[London, Female, DSD]

"And sometimes it's a bit…putting into layman's terms exactly what diabetes is, because…just so they have a better understanding of the long term effects on them or just so that they understand that it can be managed, that it's a chronic condition."

[Glasgow, Female, non-DSD]

However, in other examples, RDs referred to 'correcting' previous advice, indicating there may have been little in the way of exploration of the underlying EM of the patients.

"…it's actually readdressing some of the myths they've picked up. I can't eat grapes, or whatever it is, that kind of stuff. Or, I can't exercise without having a Mars bar first, and all that kind of stuff. I find that, depending when they've come to me, it's thinking about righting some of the perceived wrongs, or the perceived rights…"

[Birmingham, Female, DSD]

5.5 Kleinman's three social arenas (Popular, Professional & Folk)

The three arenas, also referred to as domains or sectors, form the internal structure of health care systems. The ways in which sickness is experienced can be applied to these domains across multiple cultural health care systems. Each domain is described briefly in **Table 11** and **Figure 8**.

Table 12 – Kleinman's three social arenas

Popular	Professional	Folk
Family & self-treatment is the main context. Predominant arena – who & when to consult in the professional arena is decided here. How to interpret and apply the treatments offered in the professional arena is determined here.	Includes modern medicine and indigenous healing which has been professionalized – e.g. Chinese medicine.	Includes sacred and secular healers

The three domains overlap, as shown in **Figure 9**. Kleinman [81] estimated that 70-90% of ill health or sickness is managed within the popular domain, as indicated by its size, and that people will move between the domains, whilst the popular domain remains the core and least-changing one across health care systems and cultures.[35] The domains are an organisational system in which to contain culturally-constructed 'clinical realities', which relate to the social context of sickness such as relationships, roles and expectations. As well as differing across sectors or societies, these clinical realities will differ within the same sector for each individual. In other words, each individual will develop their own clinical reality, based on their beliefs surrounding their illness. This clinical reality is core to their explanatory model and how they approach the management of their health condition. Kleinman maintains that even when health care takes place in the professional domain, that 'decisions about where and when to seek care, how long to remain in care, and how to evaluate treatment occur in the popular domain'.[33]

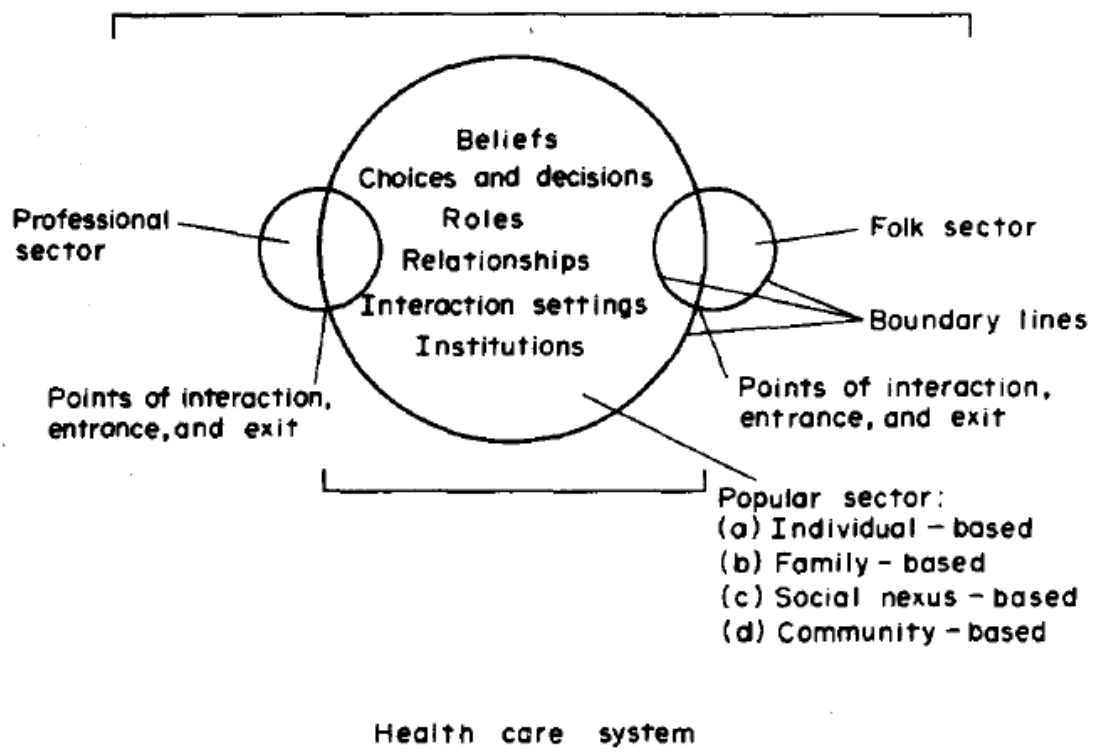


Figure 9 – Kleinman's three social arenas or domains [81]

The excerpt below provides an example of where health care provided in the professional domain was made use of and made sense of in the popular domain, supporting Kleinman's theories about health care systems.

"…insofar as what the dietitian has said has led me to do some trawling on the internet and she had a little book, you're probably aware of it…"

[P12]

Several patient participants referred to the use of the internet, television or books to support the management of their diabetes and decisions about changes to their diet.

"Well firstly we seen it in a book and then we saw it advertised on the television…"

[P13]

Similarly, RDs in the focus groups recognised that patients are receiving 'health care' from the popular sector alongside their professional advice, however it seems to be perceived as a nuisance to the RD and something which they need to attend to in a corrective manner, rather than acknowledging this as a the clinical reality of the patient and an important part of the process of developing their relationship with the patient so they become a 'therapeutic ally'.[33]

"…something or their daughter said to them something or their friend said to them something or they've read something. So you spend a lot of time answering, trying to put everything into order."

[London, Female, non-DSD]

There were no references to health care taking place in the folk sector within either the patient interviews or the RD focus groups, which may have been related to the demographic of the patients interviewed or the nature of dietitians' conversations with their patients. Examples of agents within the folk sector include herbalists and secular healers and, whilst there were no patients interviewed who referred to these, it is also possible they may not have shared this information with an interviewer perceived to be from the biomedical professional sector.[192,193]

5.6 Culturally Adaptive Tasks

Kleinman identifies 6 core adaptive tasks of health care systems, of which several are highly relevant to the findings in **Chapter Four**. Of particular note is the core task related to 'the

cultural construction of strategies and evaluative criteria to guide choices amongst alternative health care practices and practitioners and to evaluate the process and, most importantly, the outcome of clinical care'.[81] This can be applied equally to both people with T2DM (when making decisions about the source of their advice) and dietitians – who are required to navigate and interpret the research evidence for their advice as well as evaluate effectiveness at an individual or client-based level.

The 'cognitive and communicative process' which Kleinman claims includes 'labelling, classifying, and providing personally and socially meaningful explanations' [33] is also relevant to the findings. In fact, it is core to this thesis, that dietary advice regarding carbohydrate in T2DM can be improved.

'Cultural Healing' & 'Cultural Patterning'

Kleinman describes a paradox of healing deemed successful 'because the sickness & its treatment has received meaningful explanations, and related social tensions and threatened cultural principles have been dealt with appropriately, in spite of the fate of the person and his sickness'.[35] In this context the 'fate of the person and their sickness' might relate to the biomedical outcomes which are often the focus of the dietitian as part of their intervention, whereas healing refers more to the illness experience of the person with diabetes. This presents a potential disconnect between the goals of the health professional and those of the patient and understanding this may form an important stage in achieving outcomes which are deemed successful to both parties.

"I mean, an initial consultation for me, quite often, I just listen to a patient rant for ages, about every clinician they've seen… it is rapport building in the initial consultation, and then education."

[Birmingham, Female, non-DSD]

Kleinman [33] suggests that paying insufficient attention to the 'illness experience' and an overemphasis on the biomedical model of disease may be responsible for patients not following advice or for their dissatisfaction. The excerpt above highlights an important function the RD may be unconsciously performing by paying significant attention to the patient's illness experience in allowing them to "rant". The implications of this are a greater convergence of goals between the patient and practitioner and a reduction of potential problems in the future clinical care of this patient. The patient quote below serves as an example of how the patient may experience this form of cultural healing and therefore deem that she has had a positive outcome of her care, despite what the clinical outcomes may ultimately be. This particular participant spoke very highly of her experience with the dietitian, despite not fully achieving her stated goal of losing weight.

"I like to have someone to talk to. That kind of thing, not going to talk to my husband or my family, I like to talk to someone who understands what I feel… because I think that the dietitian understands why people are eating."

[P10]

When dietitians talk about the need to 'undo' previous poor advice before moving on to explain the dietary approach, this can be explained as part of the 'meaningful explanations'

that Kleinman proposes. In other words, despite the outcome of that consultation (whether the patient makes any changes, loses weight or improves their blood glucose control), the 'healing' is deemed successful because a 'meaningful explanation' was given relating to the condition. Whether this meaningful explanation serves the dietitian's explanatory model or that of the patient is not entirely clear.

Another aspect of cultural healing that is relevant to the data is what Kleinman refers to as dealing with 'related social tensions & threatened cultural principles'.[35] This relates to RDs experience regarding the lack a of clear evidence base for the quantity of carbohydrate in T2DM, or for one particular diet to be recommended T2DM. In this area there are threats and tensions coming from the influence of unqualified sources, advice from other health professionals and the media (popular domain). In the FGs, dietitians demonstrated a belief which implies they perceive themselves to be a group with 'threatened cultural principles' as they are at risk of losing their niche and authority on the subject, whilst other non-RDs are unbound by the requirement to follow a code of conduct or to use evidence-based dietary advice. This helps explain some of the RD attitudes towards others' involvement in diabetes care and potentially gives context to their enthusiasm for development of a clear guideline to help improve dietetic practice in this area, thereby strengthening the RD role and giving them greater confidence in such a role.

> *"…we can not have the local dustbin man, seriously, I'm not joking, the local dustbin man going to do a three month nutritional qualification and then thinking he can go and deliver bloody diabetes advice to patients. Because this is what's happening, this is what is happening, you can't belittle diabetes."*

[London, Female, DSD]

"…if you look on diabetes forums all they're saying is us dietitians are giving them hundreds and hundreds of grams of carbohydrate, and what you're saying is completely different. That's quite interesting."

[Cardiff, Female, non-DSD]

Despite Kleinman's theories, it could be hypothesised that these examples where cultural healing takes place contribute to what is known as 'clinical inertia' [194] in diabetes, whereby the biomedical targets are not achieved over a prolonged period of time, usually due to a lack of treatment intensification. It may be that other functions are being addressed (cultural healing) which do not fit the traditional biomedical model of health outcomes, or that there is a lack of awareness amongst health professionals of the potential value in cultural healing. In other words, paying sufficient attention to the illness experience and supporting meaningful explanations could be a starting point for creating and achieving other shared clinical goals. Dietitians might refer to this in their current vocabulary as 'rapport-building' as in the excerpt above and draw from theories and practical strategies relating to behaviour change,[195] which at a surface-level may go some way to achieving the same outcomes.

The concept of cultural patterning in illness and care relates to understanding the culture and the subsequent treatment expectations which may be inherent in that patient's culture. This may be of particular relevance in BAME groups and RDs are at risk of patients becoming dissatisfied with their care if insufficient attention is given to cultural patterning in carbohydrate advice.

"But you know in some of the ethnic groups though that fruit juice message hasn't got through, so people like Afro-Caribbean..."

[London, Male, DSD]

"Probably focus on drinks as well, because a lot of different culture things like sweet teas and things you might forget to ask about but think about it when they're from that ethnicity."

[Cardiff, Female, DSD]

The quotes above indicate that RDs do take into account cultural practices, albeit primarily from the perspective of ethnicity, and may therefore be at risk of making sweeping generalisations in that particular context, or stereotyping patients based on their ethnicity. This may then lead to advice based on assumptions rather than understanding the individual's culture, their EM and their 'clinical reality'.

Some patients interviewed made specific references to their dietitian's skills in this regard, as highlighted in Theme 1(b) in the patient analyses (Chapter Four, page 72).

"I think the dietitians need to be somewhat more aware of different diets. And when I say different diets, I'm at the risk of being...somewhat introducing race into it, culture into it. Because being of the ethnic minority, my diet is somewhat different, to say the least, from the indigenous residents of the UK, in terms of bread."

[P6]

"I think they need to go into the community, right, where it would be more helpful, because you'll have a lot of people there, you could have a lot of views there, and you could actually experience what they're eating and how it's being cooked and prepared."

[P14]

In these examples the first patient is referring specifically to the knowledge of the RD of specific foods relating to their culture and in the second the patient refers to ways in which the RD could be more effective, by affecting the preparation of food at a community level, where it is served and eaten communally. In each case it could be argued the dietitian failed to recognise the importance of cultural patterning and did not fully explore the patients' explanatory model. The patient in the second quote made several references to the difficulties in implementing advice that did not take account of the whole family, indeed the whole community, highlighting perfectly the value of a full exploration of the EM and cultural beliefs of patients.

Cultural Iatrogenesis

Iatrogenesis is an unusual word that is not used in everyday speech but can be best understood to mean problems in relation to health care, including adverse events and unintended effects. Problems in health care systems caused by 'conflicts between lay & practitioner views of clinical reality and evaluations of therapeutic success' [81] go some way towards explaining the conflict dietitians expressed in the FGs between standardisation and individualisation, and the dissatisfaction patients interviewed have with the perceived lack of individualisation from the dietitian.

"Well the information they offered was practical and common sense, you know, even a ten-year-old child could work it out, but I didn't find it helpful because I didn't lose any weight."

[P11]

The differences between the goals of patients and practitioners are therefore in-built into to the healthcare 'system' as a barrier to effective health care and may lead to iatrogenesis if the clinician does not successfully deploy their consultation skills to manage expectations and provide what the patient wants and needs. There were obvious differences in the analysis that showed what dietitians say they do and what the patients experience is not necessarily the same. Another demonstration of this was the disparity between how the dietitians define 'individualisation' of care and how the patients expected their care to be individualised. The dietitians focussed this on their own assessment of the knowledge deficit of patients, rather than attempting to understand what this means to the patient and revisiting that throughout the consultation or the episode of care.

"…but the woman was drawing little plates and can you draw little circles and I thought no, this isn't for me. I left and because, you know, I hope I'm not being arrogant by thinking I was a bit better than drawing circles on imaginary plates."

[P12]

This excerpt indicates that the RD did not fully establish the existing knowledge, needs and preferences of the patient prior to offering their advice, leading to the patient disengaging with the care offered.

The use of language & illness vs. disease

Kleinman distinguishes the meaning of the terms illness and disease as both representing different explanatory models of sickness. The differences in their use lie between the experience of the person, where the word "illness" is used, and the use of "disease" as used by the medical professions. Illness represents the lived experience of the patient and relates largely to their symptoms and how they manage these, whereas disease describes the 'malfunctioning' in a physiological sense, as it would be viewed by the healthcare professions. In diabetes there is a strong movement from diabetes charities such as Diabetes UK and from the NHS to avoid the use of the term 'Diabetic' as a noun to describe a patient and to use 'person-first' language such as 'person with diabetes'.[196] This is evident amongst the RD FGs, however in the patient interviews there were self-references to patients as "diabetics" in about half of the interviews, some of which occurred when recalling what had been said to them by health professionals. Although the prevailing term is 'people or person with diabetes', often abbreviated to PWD in the literature, it is deemed acceptable for PWD to use the term 'diabetic', however its use may be associated with labelling terms such as 'good [diabetic]' and 'bad [diabetic]' or by making generalisations.[196]

"They…they said it's forty-four and I…if it's forty-eight then diabetic and if it's, err, below forty, I'm not diabetic."

[P02]

"I've got friends that are all diabetics as well, and they let their medication control it for them."

[P08]

Furthermore, neither the words 'disease' or 'illness' are used by the medical profession or charities in diabetes, but rather it is referred to as a 'condition' which likely derives from the classification of diabetes as one of a number of 'Long Term Conditions'.[197] In this context, the professional use of the term 'condition' could be argued as interchangeable with the word 'disease', or that it is attempting to bridge the gap between the biomedical view of disease and the socially and culturally-constructed concept of 'illness'. 'Long term condition' also alludes to T2DM as permanent or semi-permanent state rather than the traditional biomedical model of disease that can be 'cured' and infers the importance of the role of the person living with the condition in its management. Whilst 'diabetes' was the term used most frequently in the RD focus groups and RDs took care to avoid the term 'diabetics' when talking about PWD, there were several uses of the term 'condition' and of the term "diabetics".

*"…I just don't think that's a good way for **diabetics** to go down, they've got to learn to eat normal food."*

[Glasgow, Female non-DSD]

*"And I think the minute you explain, well actually this is why it's important, do you know what actually the **condition** is, you know what the meds are, do you know what all of this is?"*

[Birmingham, Female, DSD]

This excerpt also has links to Kleinman's theories of why there is a greater improvement reported by patients following interactions with people in the "popular" or "folk" sectors, one of which refers to 'an increased emphasis on explanation' when compared to traditional medical practice.[35] It is suggested in this quote that the RD is taking time in the consultation

to explore EMs and to offer what has been described earlier as 'meaningful explanations' (see 'Cultural Healing'). A typical dietetic consultation is significantly longer than one with a GP [198] and therefore allows for an opportunity to spend longer on explanations. Another factor Kleinman cited for better improvements with healthcare provided in the popular and folk sectors was 'a greater concordance between the explanatory systems of healer and practitioner'.[33] It could, therefore, be argued that RDs have an opportunity to enhance their impact with more emphasis on explanation and using their consultations to explore the explanatory models of their patients and find the common ground.

"So sometimes when we do see patients sometimes you can't spend the time talking about the diabetes, it's just knowing what's causing the problems at the moment. So it could be social, economic, they've got issues with finance or if they're concerned about their condition."

[London, Female, DSD]

"Yes, I think that's probably one of the first questions I always ask, and try to find out their opinion on the matter. So, how do they feel about the diagnosis, how do they feel about their weight. And, kind of, using importance, confidence screening, but working around the reasons for, and the challenges that they face."

[Birmingham, Female, DSD]

These quotes give some indication that RDs are attempting to achieve greater congruence with the explanatory model of the patient and their own, giving the 'enhanced emphasis on explanation' that is referred to earlier and which may contribute to improved clinical outcomes and patient satisfaction.

5.7 Summary & Discussion of Kleinman's Theoretical Model Applied to the data

This analysis of the findings from **Chapter Four** using Kleinman's theoretical model has shown that there are multiple examples in the data where EMs and culturally-adaptive tasks have relevance to RD interactions with people with T2DM, and therefore to carbohydrate awareness advice in T2DM. If Kleinman's claims are correct, by considering RDs providing carbohydrate awareness as a social and cultural system, attention can be paid to undertaking the important roles and tasks within this system and therefore to improve the quality of care. It has therefore illuminated existing practice that is of benefit and suggests which aspects of practice might be enhanced. In doing so, it provides a basis on which to form the framework for carbohydrate awareness advice given that a) the meta-analysis did not provide a definitive 'one size fits all' result regarding the optimal quantity of carbohydrate, and b) no clear consensus was reached through the FGs and the interviews on some of the more specific or technical elements of carbohydrate advice that should be included in the framework.

RDs are a professional group potentially well-placed to bridge or straddle the divide between the professional and popular domains due to the opportunities they have to explore and understand the social and cultural context and to relate to patients' explanatory models of diabetes and their diet. There are a number of clear examples in the data from both the patient interviews and the RD focus groups, presented in this Chapter, that highlight the relevance of Kleinman's theory to carbohydrate advice from dietitians in T2DM. There remain questions about the practical application of this theory and how it might be incorporated into dietetic practice, which would have to be addressed in any trial examining the implementation of an advice framework based on this. Potentially useful concepts which warrant further exploration in such work would include the cultural competence of health

care practitioners such as RDs and how patients can be perceived as therapeutic allies in the health care systems. Kleinman talks about making explicit 'what is merely tacit' and this could be supported by the development and dissemination of an advice framework based on the analysis and application of theory as described in this Chapter.

A key hypothesis of Kleinman which has relevance to this thesis relates to health professionals treating both 'disease' and 'illness', whereby illness represents the patients' lived experience of disease, which is more aligned to the biomedical model. He states that 'to uncover discrepant views of clinical reality will result in measurable improvement in management and compliance, patient satisfaction, and treatment outcomes'.[33] It is possible that RDs are, at times, failing to 'uncover discrepant views…' and this may relate to some of the difficulties of patients' understanding , and subsequent implementation of, carbohydrate advice from dietitians in T2DM.

Other researchers have applied Kleinman's EMs to their work in understanding patients with diabetes. One example is the work by Poss & Jezewski [199] who studied a specific issue within a population living on the US – Mexico border. They used Kleinman's EMs to understand how Mexican Americans in Texas had combined aspects of biomedicine and traditional 'folk' beliefs to form new EMs about the development of their diabetes at an individual level, thereby emphasising the importance of exploring each individual's EM rather than making assumptions. Poss & Jezewski [199] demonstrate in their findings the effects of social contexts on explanatory models as their participates gave different types of explanations depending whether this was in an interview or a focus group setting. This has some parallels to aspects of this research, such as how patient participants' accounts of what affected their food

choices differed throughout the interview. For example, in dialogue the participants would cite various sources of information including RD advice, however in the vignette exercise the key factor driving their decisions was preference.

Weller *et al* [200] also used EMs and found that a greater congruence in beliefs between patients and providers was associated with improved clinical outcomes, a finding also reported in an older study by Cohen *et al.*[201] The research carried out for this thesis did not study health outcomes and so is not directly comparable, but the themes from the patient interviews did indicate that congruence in beliefs between patients and RDs is an important factor (section 4.2.5, page 87). In another paper, Weller *et al* [191] looked specifically at cultural competence of health care providers and concluded that, whilst important, other factors such as educational level and social class are also involved in explaining the discrepancy in lay and professional EMs in diabetes. This study did not include any measures of cultural competence of the RD and data regarding this was not collected, making it hard to identify any similarities in the data.

5.8 Conclusions & Development of the Carbohydrate Awareness Advice Framework (CAAF)

The overall aim of this research was to inform the development of a framework for improving carbohydrate awareness advice. The findings from **Chapters Two** & **Four** and the application of Kleinman's model and associated concepts described in this Chapter can now be brought together to inform the development of the CAAF. There are a number of important points in relation to these findings which will have direct relevance on the focus and contents of the CAAF, as listed below.

Key points informing the development of the CAAF:

1. Patients interviewed lacked confidence in their understanding of carbohydrate.
2. Patients interviewed often had a narrow view of carbohydrate, which is at times 'sugar-centric'.
3. Patients interviewed valued advice that is individualised, suggesting it takes account of their Explanatory Model, expressed in interviews as:
    a. Cultural & social beliefs, practices and circumstances.
    b. Existing knowledge and understanding.
    c. Preferences (types of food, types of resources etc.).
4. RDs interviewed believed individualisation of advice equates to establishing and correcting patient knowledge deficits and do not report regularly reflecting and explaining to patients how they are individualising their care.
5. RDs interviewed at times provide 'covert' advice, which is advice with a particular underlying intent that is not explained to the patient.
6. RDs interviewed felt that a patient's medication has a big influence on the types of carbohydrate advice they should give, thereby reinforcing the biomedical model.
7. RDs interviewed expressed a need for standardised language and definitions relating to carbohydrate advice yet struggle to reconcile this with patient-centred care.
8. RDs appear to lack a degree of 'cultural competence' which is compounded by failing to fully explore the patient's EM.
9. A greater congruence in beliefs and understanding the differences in EMs of patients and RDs may lead to improved health outcomes and greater satisfaction with care.

5.8.1 The Carbohydrate Awareness Advice Framework (CAAF)

The CAAF (**Figure 10**) is the culmination of the qualitative and quantitative work undertaken for this thesis. It is a graphical representation of the key findings from this research, as outlined at the beginning of this Chapter, and summarised below.

The model should form the basis for an intervention which incorporates the findings from this research. It is currently tentative; that is, it will benefit from further development and refinement as a result of its use or application in a trial or clinical setting. Each aspect of the model can be attributed to specific findings, many of which are outlined in the key points above (section 5.8, pages 154-5). Specifically, the evidence regarding quantity of carbohydrate from the Systematic Review & Meta-analysis in **Chapter Two** is represented at the bottom of the model, adjacent to the definition of 'carbohydrate awareness advice' derived from the RD focus groups. It is intentional that the person with diabetes (PWD) is represented at the centre of the model, highlighting the importance of patient-centred care and individualisation that was common to both patients interviewed and RDs in focus groups. The cog or wheel indicates a continuous cycle of confirming the wishes and preferences of PWD, also linked to individualisation, but which stems directly from the finding that this is currently seen as a one-off event that takes place only in the initial assessment. The need to explore and understand the patients' explanatory model and clinical reality points to achieving belief congruence so that patients and professionals become 'therapeutic allies'. This also highlights the need for RDs to focus on their cultural competence, an area in need of development for some dietitians, which was apparent from the patient interviews and RD focus groups. **Table 13** provides further explanation of the CAAF, including the source of each component and its suggested application.

Figure 10 – The Carbohydrate Awareness Advice Framework (CAAF)

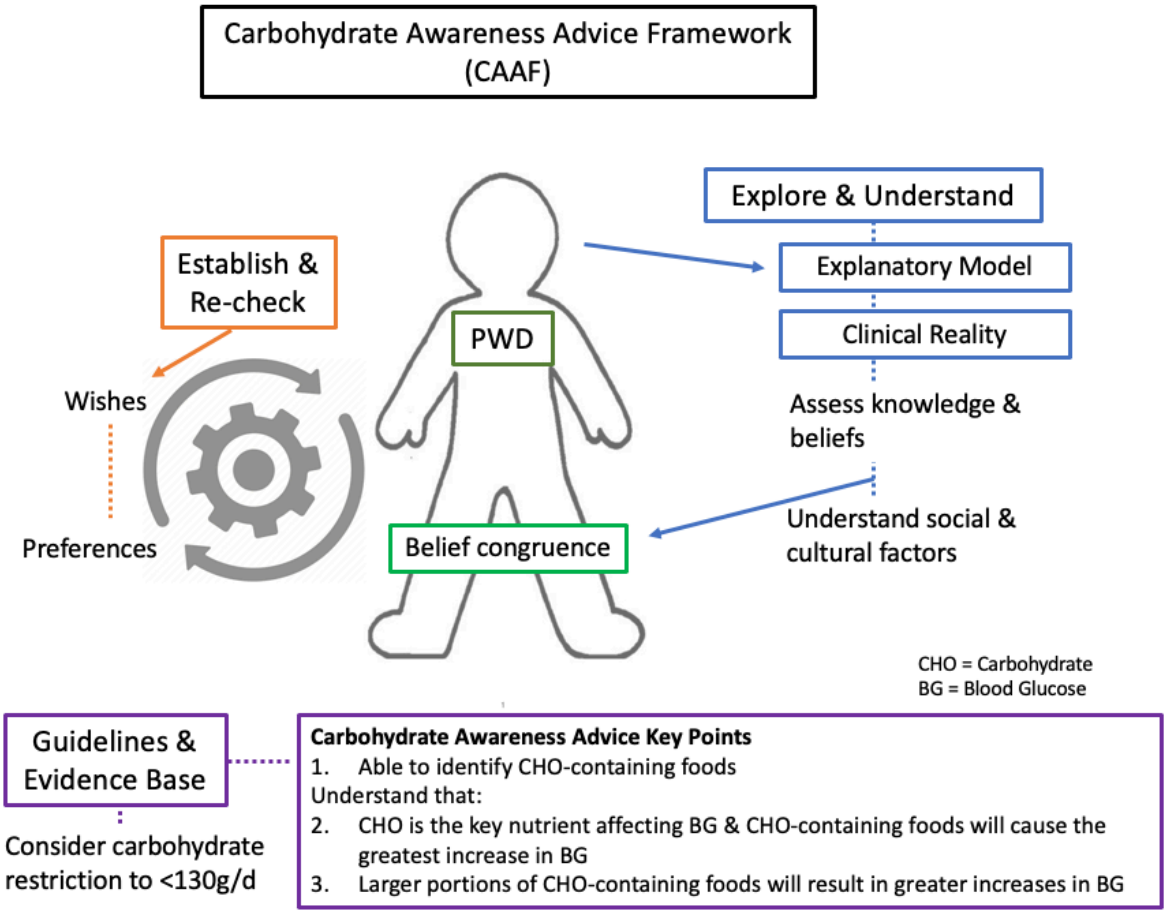


Table 13 – Explanation of the components of the CAAF

No.	Component	Research source(s)	Further Description	Application
1	Guidelines & Evidence Base	Chapter 2: Systematic Review & Meta-Analysis	This component reflects the current evidence base both from national guidelines and the systematic review & meta-analysis in Chapter 2. Carbohydrate restriction should be offered as an option to all patients and the restriction should be below 130g of carbohydrate per day.	Offers greater clarity regarding an evidence-based approach to carbohydrate awareness advice (CAA) and carbohydrate restriction. The suggested key points represent a starting point for a formal definition of CAA to be used in practice and in future research. These could form the basis of expected learning outcomes for patient resources, education sessions or consultations. Existing resources that can support the application of this component include the award-winning books and apps by Carbs & Cals.[187] Further work to refine this for use as a 'definition' and using Stakeholder groups may be incorporated into future research using the CAAF.
2	Carbohydrate Awareness Advice Key Points	Chapter 4: Dietitian Focus Groups	Carbohydrate Awareness Advice lacks a clear definition and has therefore been included in the CAAF. These key points reflect the views expressed in the dietitian focus groups. Whilst a consensus definition of the term was not the aim, nor was it appropriate for the research design, these points represent recurring themes in the views of the RDs in the focus groups.	
3	Exploring Explanatory Models & Clinical Realities	Chapter 5 – Application of Kleinman's Theoretical Model	This component represents the direct application of Kleinman's [81]	Kleinman proposed eight questions to explore patient EMs.[81] These

			explanatory models (EMs) of health care and the related concepts, particularly understanding patients' 'clinical realities'. It addresses the need for RDs to focus on patients' beliefs and to understand the social and cultural factors affecting those beliefs so that a greater degree of belief congruence can be achieved between the RD and the patient.	questions directly address the knowledge and beliefs of patients and can be applied by clinicians advising PWD. Their application will give clinicians an opportunity to reach belief congruence. Kleinman's questions could be incorporated into clinical consultations and may be included in the training of clinicians as a way of improving their cultural competence.[200] Future research using the CAAF would benefit from further exploration of examples of the use of these questions in practice and in clinician training.
4	Patient Wishes & Preferences	Chapter 4: Patient Interviews & Dietitian Focus Groups	Findings from the both the patient interviews and the RD focus groups indicated that these elements require greater attention and have therefore been included in the CAAF. Patient's wishes (or goals) are reported by dietitians as being established only at the initial assessment and do not appear to be revisited and reviewed later during an episode of care.	A number of tools and resources exist to support health professionals establish patients' goals, as part of behaviour change theory and motivational interviewing, although the most effective methods are not entirely clear.[202] This element would warrant further study in any research which implements the CAAF.

			Patients interviewed suggested that their preferences, particularly with regards to food likes and dislikes or eating patterns and the types of resources were not explored during their consultations with dietitians.	Patients will often express their goals in terms other than the biomedical language of health care professionals.[203] Professionals can therefore make use of open questions to elicit the views of patients and develop goals alongside patients in terms which are meaningful to the patient.

5.8.2 Future Research and Clinical Practice Using the Carbohydrate Awareness Advice Framework

The CAAF has been developed to form the basis of an intervention and, as outlined earlier, would benefit from further development involving Stakeholder Groups. The description & application provided in **Table 13** is intended to support the future development and practical application of the CAAF, either in clinical or in trial settings, and continues with further explanation in this section. The information in **Table 13** and in the following pages supports the 'modelling process and outcomes' part of the development stage in the MRC's framework for complex intervention development.[80]

The original intention in conducting the research for this thesis and in developing the CAAF was to provide support primarily of an instrumental nature by providing evidence-based information. The completion of the Systematic Review & Meta-analysis has served that function and therefore contributes to minimising the reducible uncertainty described in **Chapter 1**, supporting both clinical practice and future research. The results of the systematic review have an immediate impact to inform clinical practice, nutrition guidelines and provide research recommendations to improve the quality and potential impact of future studies in this field. The subgroup analysis offers greater clarity regarding the level of carbohydrate restriction required to achieve improvements in glycaemic control and weight loss and should inform the focus of future trials conducted in this field. The CAA Key Points are also instrumental in nature and could be further developed in future research trials as a core part of the intervention protocol. They would inform the development of participant resources used in any future studies and should be evaluated to asses clarity and participant

understanding or interpretation, meaning any trial using the CAAF should include a qualitative strand as a mixed methods study.

However, in completing the research and developing the CAAF it became clear that the psychosocial and relational elements of patient support are intrinsic and cannot be separated in the case of developing effective carbohydrate awareness advice. This was evident in the analysis of the patient interviews in **Chapter Four** and became increasingly clear throughout the application of Kleinman's Model, particularly with regards to connecting and interpreting the findings from both the patient interviews and RD focus groups. This highlighted a disconnect which could be addressed in part by taking account of the psychosocial and relational elements of patient support, which have therefore been incorporated in the CAAF in the form of the components which address Kleinman's EMs.[81]

Future trials based on the CAAF would benefit from incorporating or adapting Kleinman's eight questions as part of the intervention protocol.[81] These questions, or questions based on these, could then be used directly by clinicians such as dietitians in consultations in order to explore and develop an understanding of the patients' EM, achieve belief congruence and enable the clinician to deliver person-centred and culturally-acceptable care regarding carbohydrate awareness advice. Clinicians and study personnel may require additional training in the use of these questions and to develop their cultural competence before being equipped to effectively deliver the intervention. Intervention protocols would also need to include a clear consultation structure and recommended language for use by clinicians delivering the intervention, which may require further development alongside the CAAF.

Patient wishes and preferences, with regards to food likes or dislikes, the format of the information they receive and their personal goals are a central part of the CAAF and, whilst some of these aspects may be explored in an initial assessment, these are rarely re-visited later in the patient's care pathway. Intervention protocols of future trials should include the requirement of clinicians to establish a range of participant preferences and wishes at the initial consultation and to re-visit these at regular intervals throughout the study period. Additional participant resources could also be developed to support this process, such as self-directed tools to help participants identify such preferences and inform conversations with the dietitian. Study personnel may also require additional training in motivational interviewing techniques and consultation skills more generally in order to correctly and confidently implement these alternative approaches.

CHAPTER SIX

OVERALL DISCUSSION & CONCLUDING REMARKS

6.1 Introduction

This chapter will review the aims and objectives to consider whether these have been met. In doing so, it will firstly discuss the findings from the systematic review in **Chapter Two** and the qualitative work presented in **Chapters Four** and **Five** in the context of the strengths and limitations of the research, before going on to consider the practice implications and make recommendations.

6.2 Review of Research Aims, Questions & Objectives

The aim of this study was to inform the development of 'Carbohydrate Awareness Advice' as an intervention with a clear definition and framework for delivery. This was highlighted as an area of dietetic practice which lacked clarity and yet which was reported as a widely used approach in previous work.[3]

The **objectives** by which this aim was achieved were:

1. Establish the evidence base for an optimal quantity of carbohydrate in the management of glycaemia and body weight in T2DM (findings presented in **Chapter Two**).
2. Explore the experience, views and preferences of patients with T2DM with regards to carbohydrate advice, including their understanding of advice previously received from dietitians (findings presented in **Chapter Four**).

3. Explore the views, practices and preferences of RDs with regards to carbohydrate advice in T2DM (findings presented in **Chapter Four**).
4. Determine the factors that influence how RDs decide what carbohydrate advice patients with T2DM receive (findings presented in **Chapter Four**).
5. Work with a Stakeholder Group of patients and clinicians to synthesise these patient and RD perspectives, in the context of objective (1), and develop a framework for carbohydrate awareness advice which could form the basis of an intervention for use in a trial setting (findings presented in **Chapter Five**).

6.3 Discussion of findings

The detailed findings of the research are presented in **Chapters Two**, **Four** and **Five,** as noted for each objective, above. This Chapter will first provide an overall summary of the work undertaken, highlighting what is new and remarkable. It will then demonstrate how each of the research objectives has been met and position the main findings within the context of the existing literature, before considering the strengths and limitations of the research.

The meta-analysis provides evidence that restricting carbohydrate to less than 130g per day over the short term can improve HbA1c and support weight loss, however this review of the literature also casts doubt over the long-term sustainability of restricted carbohydrate diets and indicates, somewhat surprisingly, that dietary adherence is not the principal factor affecting success. People with T2DM may report a generally positive experience of receiving advice from an RD, yet their comprehension of carbohydrate remains tentative and limited, partly by their own lack of confidence. People with T2DM express a number of important views for the way in which advice should be delivered, including that it ought to take into

account their individual circumstances and preferences. RDs regard carbohydrate awareness advice a priority in T2DM yet have difficulty in clearly defining such advice. RDs also believe that patient-centred care is important, whilst simultaneously expressing a desire for standardisation of approaches, language and resources in the field of carbohydrate advice. People with T2DM and RDs hold somewhat divergent views of the concept of individualisation of advice, which may result in patient dissatisfaction with care. People with T2DM indicate that RDs lack a degree of cultural competence in delivering carbohydrate advice, which does not appear to be recognised by the RDs themselves. The application of Kleinman's theoretical model and its surrounding concepts to the findings of qualitative research involving patients with T2DM and RDs allowed for the two data sources to be connected by way of a greater understanding of the underlying social and cultural meanings and tasks undertaken. A new and adapted model of Kleinman's model and concepts (Figure 7, page 132) was developed to describe how each of these were related and how they could be used to add further interpretation to the findings from the earlier chapter. The involvement of a Stakeholder Group of people with T2DM, members of the public and other health professionals presented challenges in the delivery of the research objectives. The culmination of this work has led to the development of a novel and tentative framework for carbohydrate awareness advice that can be used in future clinical trials to inform the intervention.

The systematic review in **Chapter Two** concluded there remains some uncertainty over the optimal amount of carbohydrate patients with T2DM should consume to control their blood glucose and for weight management. It makes an important contribution to the evidence base to support existing nutrition guidelines, which state that individualisation of advice is a priority.[53] The results of the meta-analyses indicated that whilst there was no overall effect

of dietary carbohydrate restriction, sub-group analysis found that a short-term restriction to below 130g per day of carbohydrate is effective in improving both glycaemic control and weight loss. Key findings of the systematic review include a lack of adequate measurement of the pre-study diets of participants in the included studies, and the apparent difficulty participants had in adhering to the prescribed level of carbohydrate in both high-carbohydrate and low-carbohydrate arms of studies. However, a subgroup analysis of studies demonstrating dietary adherence found no difference in the outcome for glycaemic control or weight, so it is unlikely that poor dietary adherence is responsible for the lack of an overall effect of carbohydrate restriction on glycaemic control and body weight. Levels of dietary adherence in chronic disease are often reported to be low [204–206] and it is recognised as a complex and heterogenous area of health research in which to exert an effect.[207] The is further confounded by the inaccuracy in methods of dietary assessment, particularly those involving self-report.[208,209] However, the meta-analysis supports the findings of earlier reviews [54,68] and the conclusions of van Wyk *et al* [130] which indicate that the reason for a lack of overall effect in most studies, besides variable study quality, is likely to be due to a high degree of inter-individual variation in response to a number of different variables.

This lack of evidence for a 'one size fits all' definitive optimal amount of carbohydrate to recommend to all people with T2DM supports the need for an improved form of carbohydrate awareness advice by RDs and other health professionals. However, the findings from the meta-analysis should also provide additional confidence to non-specialist RDs that the level of carbohydrate restriction defined as 'Low Carbohydrate' of below 130g per day is supported by the evidence as one of the options available to their patients with T2DM. This is an

important finding in the context of a lack of confidence found in an earlier study of RD practice in this area.[3]

The results of the patient interviews indicated that the patients interviewed had a positive experience of consulting an RD. There is very little published research regarding the experience of patients receiving advice from RDs with regards to T2DM, however an Australian study [210] of patient perceptions of nutrition care from GPs in T2DM found that there is a high level (91%) of satisfaction with nutrition care from GPs, despite less than half of patients reporting having received nutrition care from their GP. This particular study was survey-based and therefore unlikely to provide a rich account of lived experience. Although positive experience and satisfaction are not entirely the same, correlations have been found between the degree of empathy shown by an RD and the level of patient satisfaction [211], thereby highlighting the importance of communication skills. Conversely, a perceived lack of usefulness of advice or repetitive advice have been cited by other research [212] as reasons for non-attendance at dietitian appointments by people with T2DM, both of which were mentioned as unhelpful by patients interviewed for this research. Patient participants expressed a clear wish for their dietetic care and advice to be individualised and for their circumstances to be taken account of, a finding also supported by the literature [213–215] and emphasised by diabetes organisations in their position statements and dietary guidelines.[216,217]

The understanding of people with T2DM with regard to carbohydrate has been the subject of one other qualitative study by Breen *et al* [218] which had similar findings to those presented in this thesis, namely that patients' understanding is relatively poor and 'sugar-centric'. Another

study found that patients misunderstood dietary fat to be the principal nutrient of interest in T2DM and cited health care professional advice as the source of their confusion.[219] A study in T1DM reported patients with better carbohydrate understanding were more likely to have attended a dietary review in the previous year, but this was not related to their glycaemic control.[220]

There is a complete lack of research examining the views or practices of RDs regarding carbohydrate advice in T2DM, besides an earlier mixed methods study which informed the development of this thesis [3] and some now outdated research which found over 90% of RDs self-reported following recommendations from Diabetes UK, then the British Diabetic Association.[221] The DAWN2 (Diabetes Attitudes, Wishes & Needs) study examined the views of health professionals in diabetes and found that whilst there is a recognised need to shift practice towards that which 'listens' more to patients, there is a perceived lack of time and resources to do so.[222] The work presented in this thesis therefore makes an important contribution to knowledge in the field of understanding the views and practices of RDs in carbohydrate advice in T2DM.

A common theme amongst research examining either the experience or perceptions of patients receiving 'advice' or 'nutrition care' is the concept of being 'patient-centred'.[210,213,223–225] A recent systematic review of the literature found that, despite difficulties around how patient-centred (or client-centred) care in dietetics is defined or in fact measured, it is 'embedded' within dietetic practice.[226] The paper also provides an ethnographic case study based on interviews with dietitians and concludes that it is useful for RDs to understand and refer to concepts of wellness and wellbeing in their attempts to

implement patient-centred care. This relates closely to Kleinman's concepts of illness vs. disease when comparing the biomedical model of sickness in comparison with the patients' lived experiences of coping with and managing their conditions. It suggests that an important aspect of being patient-centred is to first establish what the patient's definition of 'wellness' might be. Patients may continue to engage in dietetic care despite negative experiences, but may develop a sense of being disempowered,[225] potentially leading to inaction or an inability to make the necessary behaviour changes.

Two of the three South Asian patients interviewed for this thesis made particular reference to either the lack of knowledge of their RD regarding foods specific to their culture or to the lack of ease in implementing the advice. This was because it did not take sufficient account of the cultural or social constraints on their diet (such as eating food prepared centrally in community venues or eating as a whole family, most of whom had no desire to implement the same dietary restrictions). These findings are somewhat surprising given the nature of the dietetic service. It is located in Birmingham, UK, one of several UK cities with a significant South Asian population [227] and it could therefore be argued that the health professionals working in such an environment should have an awareness of these important aspects, either through experience or additional training. Similar comments have been reported in other research and, although based in Edinburgh and Oslo, people with T2DM interviewed found that health care professionals gave advice that was 'insensitive to their culture and food preferences' [228] and that health workers 'lacked sufficient knowledge about the cross-cultural variation in dietary practice relevant to ethnic minority patients.[229] A more recent meta-synthesis of qualitative research also found 'recommended diets were often incompatible with the ethnic meals consumed by the family…'.[186] These findings are consistent with the

comments made by some of the patients interviewed for this thesis and relate to the concept of 'cultural competence' that was referred to in **Chapter Five**. It suggests that learning from other research has not yet influenced the practice of the RDs who advised the patients interviewed for this thesis, or that RDs have an inaccurate perception of their own degree of cultural competence.

A study regarding the experience of patients receiving dietetic counselling provides a further example of how the Kleinman model is applicable to this subject area [223], although the authors did not use or cite Kleinman. The title of the paper is based on a quote from the findings of the study 'If you listen to me properly, I feel good' and in fact captures neatly one aspect of Kleinman's 'Cultural Healing' where meaningful explanations are deemed an important part of the healing process, and both satisfaction with care and clinical outcomes are improved when the patient's explanatory model is fully explored and understood. In accordance with the findings presented in **Chapter Four**, Hancock *et al* [223] found that patients feel it is important for the RD to 'discover details about them as an individual and tailor the intervention accordingly', which agrees with the findings in this thesis regarding individualisation, however the authors found that not all patients preferred a patient-centred approach with some preferring a prescriptive style. This could also be linked with a finding in **Chapter Four** in which patients interviewed were said to find advice on 'what to eat or not eat' helpful. In contrast, a qualitative study by Ball *et al* [224] found that patients with T2DM found prescriptive, guideline-based advice from RDs unhelpful and potentially confusing or conflicting. The authors found there was a clear desire in the patients interviewed for the care from the dietitian to be individualised and 'tailored to individual circumstances' [224] which also corresponds closely with the findings presented in this thesis. Despite the claim by Kleinman

that 70-90% of health care takes place in the popular domain,[81] studies of information-seeking behaviour indicate that the health care professional in diabetes is important in validating information that patients may have found elsewhere, such as the internet.[31]

It was not an original aim of the research to make a direct comparison across the findings from the patient interviews and the RD focus groups, however one striking difference is worthy of discussion. The concept of 'individualisation' was discussed by both groups, particularly by the RDs as an important aspect of their approach. However, in the analysis of the RD focus groups and the patient interviews, it was clear that both groups understood the term differently. Whereas RDs referred to 'individualisation of advice' to mean identifying knowledge deficits and targeting advice accordingly, the patient participants intended for their health professional to learn about their lifestyle, their likes and dislikes, and to take account of their existing knowledge in tailoring the advice to their needs. This conflict in how advice is directed has the potential to lead to dissatisfaction from patients, if they perceive they are not receiving the advice they need or desire. In fact, this is supported by research in people with T2DM that found guideline-based nutrition care was not sufficiently adapted to their needs and who did not feel that advice from a dietitian would be useful.[224] Other research has suggested that nutrition guidelines in diabetes need to be more patient-focused.[230] An integrative review of literature found that a positive dietitian-patient relationship and individualizing and adapting care were both important elements of person-centred care.[213]

Other research has defined RD engagement styles as helpful or unhelpful in the context of the extent to which they are patient-centred.[225] The authors applied the model of

Transactional Analysis to their findings, whereby the parent (critical or nurturing) ego state was related to an unhelpful engagement style and found subthemes such as 'patronising tone' and 'not listening to our needs' as unhelpful; whereas 'understanding of my situation' was one of the helpful subthemes. This does draw parallels with some of the findings from **Chapter Four** with regard to 'helpful' advice that patients identified. In many cases the patients were not in fact referring to specific factual elements of the advice, but rather the way in which the RD interacted with the patient in delivering the advice. For example, patients preferred advice that was not patronising and took account of their existing knowledge, experience and cultural and social circumstances. This matches closely with the adult-adult relationship as defined using a model of Transactional Analysis [231] and so has some relevance to the work undertaken in this thesis. However, the model of Transactional Analysis alone would not have added the level of interpretation that Kleinmans's models have because it focusses primarily on understanding the relationship between the RD and patient, or the communication style of the RD, rather than the wider social and cultural nature of healthcare systems that is encompassed in explanatory models.

6.4 Contributions to knowledge

The findings from this thesis make an important and original contribution to knowledge and understanding in the field of carbohydrate advice in T2DM. It is the first study of its kind to investigate both the experience of patients with T2DM who have received advice from an RD, and the views and opinions of dietitians regarding carbohydrate advice in T2DM. In addition, the meta-analysis added an important finding to the literature regarding the impact of dietary adherence on outcomes for low carbohydrate diets.

This is not the first study to use Kleinman's model in understanding aspects of T2DM but it is the first to apply the theories to qualitative data regarding carbohydrate advice and then to apply this to the development of an advice framework. The framework itself (section 5.8.1, page 153) represents a novel contribution to the field and forms the basis for an intervention which may go on to be used in clinical trials.

6.5 Strengths of the study design

There are a number of strengths in the design of this study, in particular the use of a mixed methods research (MMR) approach to answering the research questions. The MMR approach in this study brought together both patients' and RDs' experiences and used the published research to provide a quantitative response in the meta-analysis. Alongside the application of a theoretical model applied at the integration and interpretation stage, this has provided the opportunity to gain a rich understanding of carbohydrate advice in T2DM and has led to the formulation of a framework that may lead to further research and inform future clinical guidelines for RDs in T2DM.

MMR can suffer from a lack of transparency in the planning and reporting of studies, as reported by other researchers to the extent that some researchers appear unclear in the purpose of MMR in their research.[232] Guidance has been suggested to improve the reporting of MMR, known as 'Good Reporting of a Mixed Methods Study' (GRAMMS).[233] A strength of the research reported in this thesis is its ability to demonstrate adherence to this guidance. O'Cathain *et al* [233] also found that reports of MMR often describe the quantitative elements more fully than the qualitative elements, which is not the case in this research study.

Figure 11 – Good Reporting of A Mixed Methods Study (GRAMMS)

Box 1 Good Reporting of A Mixed Methods Study (GRAMMS)

(1) Describe the justification for using a mixed methods approach to the research question
(2) Describe the design in terms of the purpose, priority and sequence of methods
(3) Describe each method in terms of sampling, data collection and analysis
(4) Describe where integration has occurred, how it has occurred and who has participated in it
(5) Describe any limitation of one method associated with the present of the other method
(6) Describe any insights gained from mixing or integrating methods

Figure 11 outlines the six questions that form part of GRAMMS, however these questions are enhanced with the addition of a seventh question, "Is the whole greater than the sum of the parts?" It is argued that the work presented in this thesis is able to answer affirmatively in response to the six questions of GRAMMS, and the additional seventh question

The mixed methods approach used in this research study falls under the typology of 'convergent parallel design',[234] meaning that both the quantitative (Systematic Review, **Chapter Two**) and Qualitative (Patient Interviews & RD Focus Groups, **Chapters Four** & **Five**) were undertaken without a need for one to directly inform the development of the other. These elements of the research were answering different research questions, aimed at achieving the same overall aim of the research. As is often the case in MMR, priority is given to one element [234] and in this case priority was given to the qualitative work within this thesis, on the basis that the existing research regarding carbohydrate and T2DM is yet still unable to give definitive answers and uncertainty remains. Integration took place in **Chapter Five** in the

development of the framework for carbohydrate awareness advice. The value of MMR in health services research has been described elsewhere,[235,236] but in particular the integration of quantitative and qualitative methodologies can be of use when developing a theory or instrument, as is the case in this thesis.

The use of Kleinmans' theoretical model is a clear strength in the analysis and interpretation of the qualitative data for this thesis. One valuable output for the application of a theoretical model to the data was the development of the conceptual framework (Figure 7, page 132) which is an adapted version of Kleinman's [35] model designed to show visually 'how existing ideas in the literature work together'.[237] This visual representation of how Kleinman's theories have been brought together to add further interpretation helps in understanding a potentially complex field. Other models were considered and have been discussed elsewhere in this work, e.g. Transactional Analysis [231] (section 6.3, page 163).

The FGs running in two rounds allowed for some percolation of the information obtained and shared amongst participants, as well as the opportunity to share some of the initial findings from the patient interviews at the start of the second round of FGs. On reflection, another advantage was for the facilitator to gain an insight into the level of knowledge of the current guidelines and evidence base within each FG. One group in particular was unaware of the most recent guidelines, which at that time were the 2011 Diabetes UK Nutrition guidelines.[53] This time between the two FGs provided the opportunity to share the most recent guidelines and some other papers with all of the FGs, so that there would be a similar level of understanding of current evidence in carbohydrate and T2DM.

6.6 Limitations of the study design

There are a number of limitations of the study design, several of which are common to many research studies.

Selection bias is a potential risk in both of the qualitative strands of this research, meaning there is a chance that those who took part in the study represent a particular set of views from a population of individuals with a special interest in the subject area. Whilst qualitative research does not claim 'generalisability' to a wider population through statistical inference, it does intend to have validity and reliability [238] through a clear and rigorous methodology. The purposive sampling used in the patient interviews may have resulted in a disproportionate number of patients with T2DM agreeing to be interviewed with a previous negative or conversely positive experience of seeing an RD. Whilst positive response bias has been reported in patient satisfaction surveys,[239] and the data presented in **Chapter Four** does indicate patients with T2DM interviewed had generally positive experiences with their RD, there were several examples of critical comments in interviews, suggesting that a bias is unlikely. Of course, it is possible that people who did not take part held different views. Similarly, there is a risk that RDs who came forward to take part in the focus groups did so to express a particular viewpoint in favour of (or against) particular approaches to carbohydrate advice in patients with T2DM. However, as with the patient interviews, there was little evidence of this in the FGs and the nature of FG methodology means that this risk should be attenuated through proper group facilitation.

The intention of including a Stakeholder Group was to improve the quality of the research outputs and, in particular to support more effective recruitment to the patient interviews [169].

However, despite their engagement and enthusiasm, the Stakeholder Group did not have a significant impact on recruitment for patient interviews. The SG members were diverse with regards to their backgrounds and personal or professional interest in the research topic, however on occasion it was challenging to engage them in a way which resulted in the desired outcome. During SG meetings, some members demonstrated a personal bias or misunderstood the aims and objectives of the research. This is principally the responsibility of the researcher and may be due to the late stage at which SG members were recruited and engaged. With regards to the 7-item stakeholder engagement reporting questionnaire,[173] there was a lack of engagement before the research began, which may have led to the limited impact during the research activities. There is little published research that highlights this potential pitfall in public and patient involvement in research, however it has been described as 'scope creep' in one systematic review,[240] and it may have been a factor in this research. Other research has concluded that these types of patient and public involvement groups are more impactful in the early stages of planning a research project and less so in the running and delivery.[168] Furthermore, none of the SG members took up the offer of additional training in research methods or diabetes, and time during SG meetings was limited, with a reluctance on the part of the researcher to expect SG members to dedicate much of their own time outside of meetings to reviewing and understanding study documentation.

Although studying regional variations in practice was not an explicit aim of the qualitative study, the RD focus groups were unable to generate direct geographical comparisons, or to detect important regional variations in practice. It was a conscious decision to hold FGs in different locations across the UK due to the potential for variations in practice, but only minor differences were observed. This may have been due to the number of groups conducted or

the number of participants in each group, for example in one location the FG ran with only three participants. It may also have been necessary to carry out more groups in each location to achieve this. The FGs were intentionally comprised of both specialist and non-specialist RDs, however this approach might have led to a dilution of the themes where specialists and non-specialists may have diverged in their views, had they been separated into different focus groups. This corresponds with earlier findings that differences exist between specialists and non-specialists in their confidence to provide different types of carbohydrate advice,[3] however other researchers have also found that combining specialists and non-specialists in single groups does not impede communication,[124] and therefore it is unlikely that those differences would have been suppressed in a mixed group setting. It could therefore be argued that such differences would have been apparent. Furthermore, if the specialists and non-specialists had been separated into different groups, it is likely that more FGs would have been required and recruitment and resources (time and funding) would have been a limiting factor in running more than the eight focus groups.

The demographics of the sample for the patient interviews were somewhat different to the whole population in the database from which it was drawn in that there was a higher proportion of male participants, and they were slightly older (Table 6, page 57). With regards to the UK population of people with T2DM, given that there are over 3 million people living with T2DM in the UK it is unlikely that their demographics are similar enough to make a comparison at a national level useful.

6.6 Reflections on methodology

The rationale for the methodology for the qualitative research is outlined clearly in **Chapter Three**. A range of methods were justified on the basis of answering a number of different research questions, and the application of a theoretical model has been both justified and demonstrated to increase the value of the findings in **Chapter Five**.

It is possible that other methodologies and typologies of MMR could have been employed in this research, such as a sequential multi-phase design, in which multiple elements or stages of both quantitative and qualitative work could have been conducted in an attempt to further clarify and prioritise elements of carbohydrate advice from the patient and RD findings. For example, Q Methodology [241] or the Delphi method [242] might have been applicable if this approach had been chosen, however this would have implied that it was either possible or desirable to achieve a singularly 'correct' approach that does not fully take account of the need for 'individualisation' or 'person-centred' care, particularly from the perspective of the person with diabetes. These are two concepts that have been given some importance in the development of the framework because of the large degree of uncertainty and inter-person variation that is likely to remain within this field. It is the MMR approach employed in this thesis that has allowed the construction of the CAAF, and therefore contributed to achieving the aim of the research.

Data (thematic) saturation was employed in the qualitative analysis of the patient interviews in **Chapter Four**, however Malterud *et al* [243] has proposed the concept of 'information power' as an alternative to data saturation, meaning the required number of participants depends on a number of factors including, but not limited to, how broad the aim of the study is and

how specific the sample is. In the case of the current research, despite there being a number of elements of information power that could be applied, it was felt that the traditional approach of data saturation was more suited.

6.7 Implications for practice and policy

The Profession and practice of dietetics are relatively new, as is the science of nutrition, particularly nutrition therapy in either chronic disease management or the prevention of chronic disease. Early nutrition science was concerned with the avoidance of deficiency [244] however this has now shifted toward the dietary 'optimisation' of health and subsequently led to the creation of an entire industry centred around diet. Nutrition information is ubiquitous in all forms of the media and with frequently low levels of accuracy in the reporting of such information.[245] In many modern societies, individuals are faced with an abundance of food [246] and are therefore required to make frequent decisions about what to eat. This is just a part of the constantly evolving context in which RDs are required to provide effective carbohydrate advice to patients with T2DM.

As discussed in **Chapter One** and **Chapter Two**, there is conflicting evidence and even controversy regarding the optimal amount of carbohydrate people with T2DM should consume, and this has led to a lack of confidence and variation in practice amongst RDs.[3] This thesis has contributed to reducing the uncertainty through the systematic review and meta-analysis, which provides greater evidence to support nutrition guidelines and should enable health care professionals to be more confident in supporting patients who wish to follow a low carbohydrate diet for T2DM. In addition, by enhancing the understanding of patients' and professionals' views and providing a carbohydrate advice framework which is based on a

robust theoretical model, the 'subjective uncertainty' [67] inherent even in evidence-based medicine has also been reduced.

The CAAF outlined and described in **Chapter Five** remains tentative at this stage. The framework, whilst based on the findings of this research and the application of a strong theoretical model, has yet to be tested or applied to the practice of advising people with T2DM about carbohydrate. The ideal setting in which to do this would be a clinical trial, however it is expected that this may require some further interpretation of the model in order to develop the detailed intervention and to guide RDs in their consultations with people with T2DM.

6.8 Recommendations for future research

This thesis has informed future research in a number of ways. The systematic review and meta-analysis provided insight into the limitations of the body of evidence from trials of restricted carbohydrate diets. The addition of the qualitative work has led to the development of the CAAF, Figure 9, which has the potential to directly inform future research. As such, the research recommendations resulting from this thesis are:

1. Any future RCTs of restricted carbohydrate diets should attempt to keep both study arms isocaloric, accurately measure the pre-study diet of participants and should continue for longer than 12 months.
2. Future RCTs of carbohydrate restricted diets should adopt a MMR approach and incorporate a nested qualitative study to examine the experience of participants and attempt to determine social & cultural factors which will predict success with carbohydrate restriction.

3. The CAAF should be used to inform future research studies examining the effectiveness of carbohydrate awareness advice and should form the basis of the intervention.

6.9 Concluding Remarks

In conclusion, this thesis has developed our understanding of the views, preferences and practices of people with T2DM and RDs with regards to carbohydrate awareness advice. It has demonstrated that a theoretical model first developed over 40 years ago has significance in illuminating the cultural and social nature of the care provided by RDs. However, more importantly, it has proposed a framework for using the concepts surrounding the theoretical model to deliver carbohydrate advice to people with T2DM in the context of uncertainty regarding the optimal amount of carbohydrate. This framework has the potential to improve how RDs advise people with T2DM about carbohydrate and as such it warrants further study in the form of a trial.

LIST OF APPENDICES

LIST OF REFERENCES

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PUBLICATIONS: PAPERS AND PRESENTATIONS

This section lists relevant publications and presentations that have occurred throughout the period of this thesis, some of which are cited in the text.

Papers (First Author & Co-Author)

Dyson P, **McArdle P**, Mellor D, et al. James Lind Alliance research priorities: what role do carbohydrates, fats and proteins have in the management of Type 2 diabetes, and are there risks and benefits associated with particular approaches? *Diabetic Medicine*, 2018. Epub ahead of print 2018. DOI: 10.1111/dme.13826.

Dyson P, Twenefour D, Breen C, Duncan A, Elvin E, Goff L, et al. Diabetes UK evidence-based nutrition guidelines for the prevention and management of diabetes. Diabet Med. 2018;35(5):541–7.

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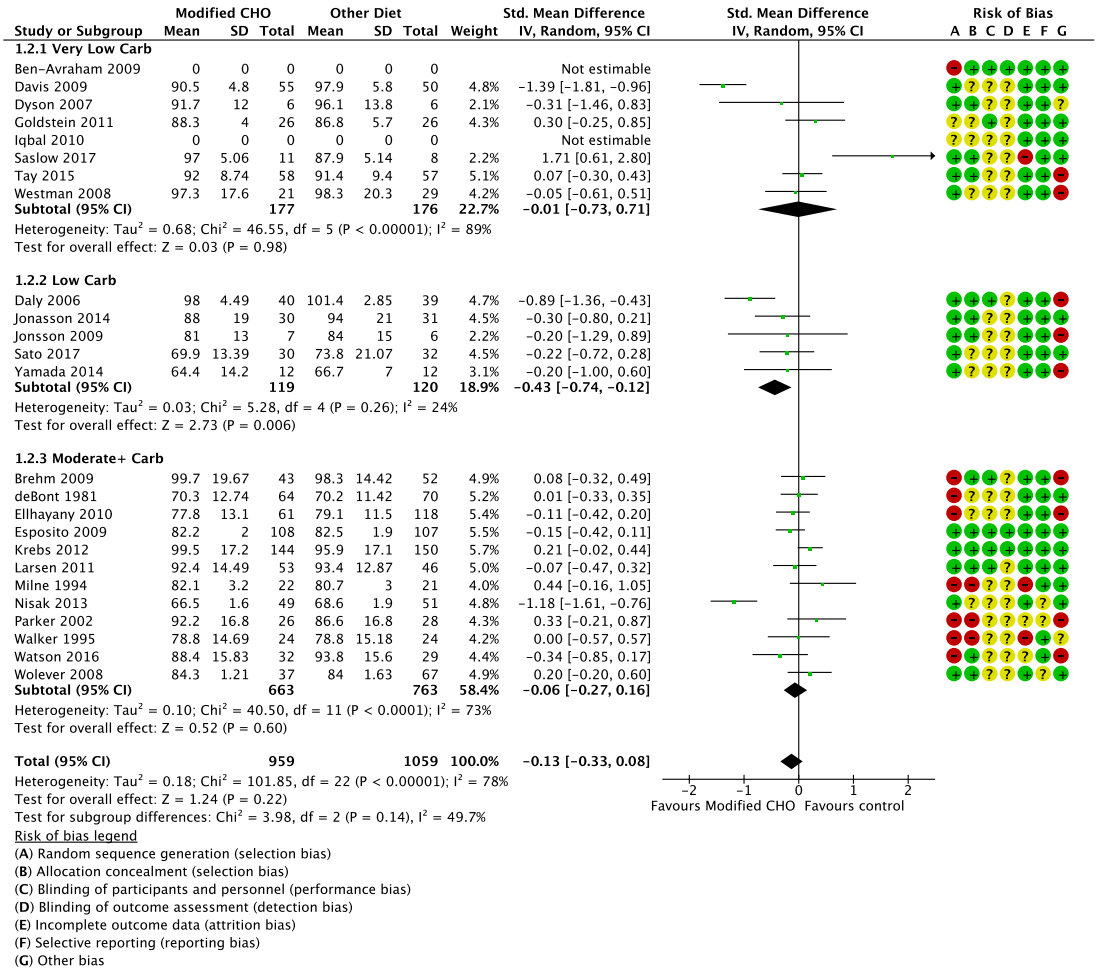
Conference Abstract (Poster)

McArdle P, Gill P, Greenfield S. Quantity of Carbohydrate in Type 2 Diabetes: A Systematic Review. Poster presented at: 77th Scientific Session of American Diabetes Association; 2017 June 9-13 ; San Diego.

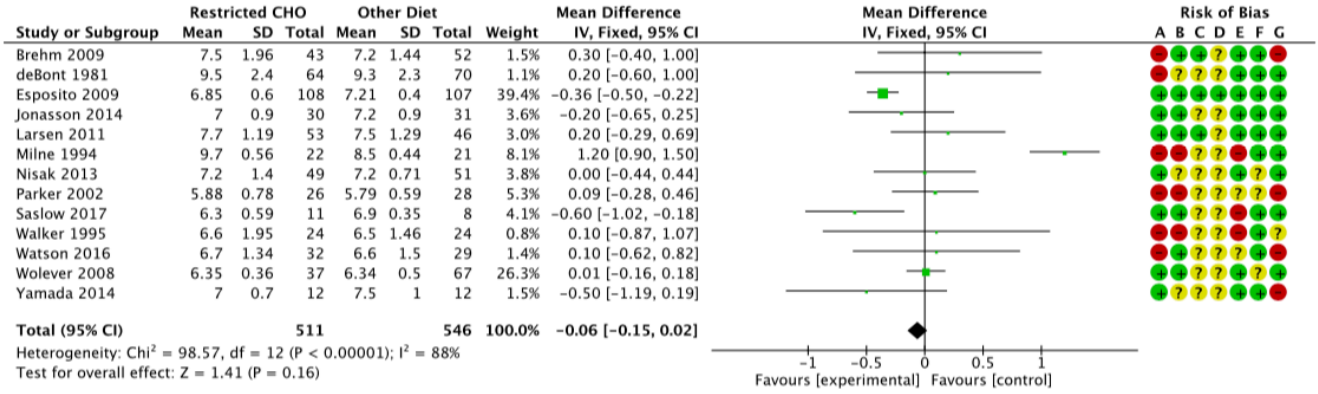
Appendix One

Figure S1. Forest Plot for Body Weight



Appendix Two

Figure S2. Forest plot for HbA1c for studies reporting adherence to restricted carbohydrate diet.



Risk of bias legend
(**A**) Random sequence generation (selection bias)
(**B**) Allocation concealment (selection bias)
(**C**) Blinding of participants and personnel (performance bias)
(**D**) Blinding of outcome assessment (detection bias)
(**E**) Incomplete outcome data (attrition bias)
(**F**) Selective reporting (reporting bias)
(**G**) Other bias

Appendix Three

Table S1. Results of individual studies: blood pressure & lipids

Author, Year	Baseline										Post-intervention									
	Modified Carbohydrate					Control / Other Diet					Modified Carbohydrate					Control / Other Diet				
	SBP mmHg	DBP mmHg	TC mmol/l	LDL-C mmol/l	HDL-C mmol/l	SBP mmHg	DBP mmHg	TC mmol/l	LDL-C mmol/l	HDL-C mmol/l	SBP mmHg	DBP mmHg	TC mmol/l	LDL-C mmol/l	HDL-C mmol/l	SBP mmHg	DBP mmHg	TC mmol/l	LDL-C mmol/l	HDL-C mmol/l
Very Low Carb																				
Ben-Avraham, 2009 [b]	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
Davis, 2009 [c]	125 (18)	73 (9)	4.4 (0.83)	2.5 (0.69)	1.3 (0.24)	130 (17)	37 (6)	4.3 (0.86)	2.4 (0.74)	1.2 (0.29)	127 (15.6)	70.1 (9.4)	4.5 (0.76)	1.26 (0.63)	1.46 [a] (0.27)	128.2 (22.6)	34.8 (11.6)	4.17 (0.7)	2.22 (0.66)	1.26 [a] (0.21)
Dyson, 2007	NR	NR	4.8	2.70	1.24	NR	NR	4.7	2.69	1.47	NR	NR	4.8	2.94	1.32	NR	NR	4.6	2.75	1.34
Goldstein, 2011	140 (17)	79 (10)	5.02 (0.65)	NR	1.14 (0.33)	135 (14)	80 (9)	5.17 (0.96))	NR	1.14 (0.26)	127 (38)	70.7 (19)	4.81 (0.75)	NR	1.25 (0.18)	131 (12)	86.2 (7)	5.12 (0.54)	NR	1.28 (0.23)
Iqbal, 2010 [d]	139.7 (20.1)	78.8 (10.3)	4.66 (1.20)	2.83 (1.0)	1.06 (0.33)	140.1 (19.8)	80.0 (12.2)	4.67 (1.07)	2.79 (0.96)	1.05 (0.33)	136 (*4.3*)	77.6 (*2.1*)	4.64 (*0.19*)	2.71 (*0.16*)	1.12 (*0.03*)	130.4 (*3.2*)	75 (*1.9*)	4.46 (*0.19*)	2.57 (*0.15*)	1.08 (*0.03*)
Saslow, 2017 [e]	NR	NR	NR	2.51 (0.79)	1.18 (0.39)	NR	NR	NR	2.34 (0.75)	1.39 (0.33)	NR	NR	NR	2.50	1.31	NR	NR	NR	2.18	1.41
Tay, 2015	130.4 (13.1)	80.0 (8.9)	4.5 (1.0)	2.5 (0.9)	1.2 (0.2)	132.6 (13.2)	80.8 (10.1)	4.3 (1.0)	2.4 (0.9)	1.3 (0.3)	123.3	73.8	4.4	2.4	1.3	126.8	74.4	4.2	2.2	1.36
Westman, 2008	144.4 (15.0)	83.9 (10.3)	4.95 (0.83)	2.74 (0.66)	1.14 (0.22)	140.8 (15.7)	84.1 (11.0)	4.93 (1.13)	2.94 (1.06)	1.26 (0.30)	127.8 (13.4)	75.8 (10.9)	4.84 (0.93)	2.77 (0.68)	1.28 (0.30) [a]	130.1 (17.1)	78.5 (8.7)	4.78 (1.18)	2.87 (1.09)	1.26 (0.26) [a]
Low Carb																				

Daly, 2006 [f]	145.5 (2.54)	79.9 (1.43)	4.85 (0.12)	NR	1.20 (0.04)	138.8 (2.34)	79.0 (1.53)	4.94 (0.15)	NR	1.21 (0.06)	139.3 (2.96)	NR	NR	NR	NR	138.4 (0.13)	NR	NR	NR	NR
Jonasson, 2014	NR	NR	4.5 (1.0)	2.7 (0.9)	1.1 (0.3)	NR	NR	4.3 (1.0)	2.4 (0.7)	1.1 (0.3)	NR	NR	4.4 (1.1)	2.5 (0.8)	1.2 (0.5)	NR	NR	4.2 (1.1)	2.3 (0.8)	1.1 (0.3)
Jonsson, 2009	156 (23)	83 (11)	4.2 (1.3)	2.7 (1.0)	1.28 (0.25)	144 (18)	84 (9)	4.7 (0.9)	3.0 (0.8)	1.28 (0.19)	140 (12)	79 (6) [a]	4.3 (1.2)	2.7 (1.0)	1.34 (0.30) [a]	149 (22)	83 (9) [a]	4.5 (1.2)	2.8 (1.1)	1.26 (0.23) [a]
Sato, 2016 [g]	NR	NR	NR	2.62	1.12	NR	NR	NR	2.50	1.22	NR	NR	NR	2.48	1.25	NR	NR	NR	2.65	1.24
Yamada, 2014	124.4 (10.8)	72.6 (6.2)	NR	2.58 (0.73)	1.62 (0.44)	124.9 (10.7)	74.8 (10.6)	NR	2.90 (0.53)	1.55 (0.49)	122.5 (11.9)	66.6 (9.4)	NR	2.46 (0.54)	1.76 (0.57)	121.3 (11.6)	73.4 (10.1)	NR	2.86 (0.56)	1.44 (0.36)
Moderate+ Carb																				
Brehm, 2009 [h]	132 (2.3)	78 (1.4)	179 (7.2)	104 (7.0)	42 (1.2)	130 (2.0)	77 (1.6)	178 (4.9)	100 (4.6)	43 (1.4)	130 (2.4)	73 (1.5)	184 (6.5)	101 (6.1)	47 (1.3)	129 (2.3)	73 (1.4)	180 (5.2)	97 (4.9)	48 (1.4)
deBont, 1981 [i]	NR	NR	7.32	NR	1.99	NR	NR	7.57	NR	1.96	NR	NR	7.04 (*0.99*) [a]	NR	1.80 (*0.43*)	NR	NR	6.67 (*1.09*) [a]	NR	1.87 (*0.40*)
Ellhayany, 2010	NR	NR	5.38 (0.97)	3.07 (0.81)	1.08 (0.23)	NR	NR	5.41 (0.87)	3.12 (0.81)	1.07 (0.19)	NR	NR	4.5 (0.85)	2.46 (0.72)	1.21 (0.21) [a]	NR	NR	4.5 (0.70)	2.65 (0.74)	1.05 (0.20) [a]
Esposito, 2009	139 (12)	87 (8)	5.7 (0.9)	NR	1.1 (0.2)	140 (12)	86 (8)	5.6 (0.9)	NR	1.1 (0.2)	136.5 (*1.5*)	84.1 (*1.9*)	5.5 (*0.2*)	NR	1.19 (*0.08*)	139 (*1.0*)	84.5 (*1.5*)	5.5 (*0.18*)	NR	1.12 (0.07)
Krebs, 2012	131.1 (14.8)	76.8 (10.3)	4.77 (0.98)	2.74 (0.91)	1.09 (0.32)	130.6 (17)	76.6 (11)	4.61 (1.03)	2.67 (0.92)	1.11 (0.28)	133.3 (24)	76.5 (11.1)	4.53 (0.98)	2.57 (0.93)	1.08 (0.30)	131.6 (20.2)	76.2 (11.6)	4.44 (1.07)	2.47 (0.93)	1.13 (0.32)
Larsen, 2011 [j]	131.8	81.5	4.73	2.49	1.19	127.4	81.5	4.71	2.42	1.20	NR	NR	4.57	2.44	1.27	NR	NR	4.70	2.46	1.28
Milne, 1994 (SE)	NR	NR	6.0 (0.2)	4.2 (0.20)	1.15 (0.10)	NR	NR	6.6 (0.33)	4.2 (0.31)	1.23 (0.07)	NR	NR	5.7 (0.15)	3.6 (0.15)	1.22 (0.06)	NR	NR	6.2 (0.2)	4.0 (0.19)	1.19 (0.06)

Nisak, 2013 [k]	139.2 (19.2)	79.3 (8.2)	4.56 (0.8)	2.78 (0.67)	1.18 (0.34)	127.5 (15.4)	76.8 (9.95)	4.54 (0.75)	2.78 (0.67)	1.08 (0.30)	137.0 (2.3)	79.2 (1.3)	4.8 (0.16)	2.93 (0.14)	1.21 (0.05)	127.5 (2.0)	75.2 (1.2)	4.54 (0.12)	2.67 (0.11)	1.14 (0.04)
Parker, 2002	NR	NR	5.16 (0.17)	3.32 (0.16)	0.93 (0.03)	NR	NR	5.16 (0.25)	3.23 (0.20)	0.95 (0.05)	NR	NR	4.81 [a] (0.16)	3.13 [a] (0.15)	0.92 (0.04)	NR	NR	5.15 (0.25)	3.32 (0.22)	0.96 (0.03)
Walker 1995 [l]	133 (3)	77 (2)	5.98 (0.24)	3.81 (0.17)	0.99 (0.05)	132 (3)	74 (2)	5.75 (0.18)	3.62 (0.18)	1.02 (0.05)	134 (4)	76 (2)	5.93 (0.19)	3.82 (0.15)	1.04 (0.05)	130 (4)	74 (2)	5.86 (0.24)	3.64 (0.18)	1.02 (0.06)
Watson, 2016 [m]	131.8 (13.2)	78.4 (8.2)	4.7 (0.9)	2.7 (0.9)	1.2 (0.3)	135.1 (8.3)	79.0 (7.1)	4.5 (0.8)	2.5 (0.6)	1.2 (0.3)	119.5 (2.3)	70.7 (1.6)	NR	NR	NR	125.2 (2.3)	74.1 (1.6)	NR	NR	NR
Wolever, 2008	127 (3)	78 (2)	5.01 (0.13)	3.02 (0.1)	1.16 (0.05)	126 (3)	77.5 (1.5)	4.98 (0.14)	2.93 (0.13)	1.18 (0.04)	127 (1)	NR	4.99 (0.08)	2.89 (0.05)	1.21 (0.03)	128.5 (1)	NR	5.04 (0.08)	2.96 (0.06)	1.17 (0.03)

Data are mean (SD) – where available or SE/ SEM (noted)
NR = not reported
SBP = Systolic Blood Pressure
DBP = Diastolic Blood Pressure
TC = Total Cholesterol
LDL-C = Low Density Lipoprotein Cholesterol
HDL-C = High Density Lipoprotein Cholesterol
[a] significant between-group difference
Where separate baseline values are not reported, the entire cohort values are used for both groups
Values for cholesterol converted from mg/dl to mmol/l for Goldstein, Iqbal, Westman, Sato & Yamada
Figures in ***italics*** indicate SD/SE is for the change / difference
Further notes:
[b] **Ben-Avraham** – patients with diabetes part of larger study cohort, not all data reported separately
[c] **Davis** – outcome data includes SD for the change/difference only, not the mean – used in meta-analysis
[d] **Iqbal** – figures in brackets post-intervention are SE
[e] **Saslow** – post-intervention figures based on changes from baseline. P values and CIs available for change.
[f] **Daly** – figures in brackets are SEM
[g] **Sato** – confidence intervals available

[h] **Brehm** – figures in brackets are SEM
[i] **deBont** – weight data is a sub-set of overweight patients only (n=69). SD only available for change.
[j] **Larsen** – confidence intervals available (no SD / SE)
[k] **Nisak** – figures in brackets are SE
[l] **Walker** – figures in brackets are SE
[m] **Watson –** figures in brackets for post-intervention are SEM

Appendix Four

Table S2. Carbohydrate: baseline vs. prescribed vs. actual and methods of dietary assessment.

Author, Year	Baseline Carbohydrate Intake g per day		Prescribed Carbohydrate Intake g per day		Actual Carbohydrate Intake g per day – longest time point		Method of dietary assessment
	Restricted Carb	Control	Restricted Carb	Control	Restricted Carb	Control	
Very Low Carbohydrate							
Ben-Avraham, 2009 [b]	254	258	20	Unclear	147	193	Validated FFQ
Davis, 2009	218	192	20-25 [c]	Unclear	137	227	24h recall & daily food diary
Dyson, 2007	223	223	<40	142	57 [a]	167	Validated 3-day food diary
Goldstein, 2011	213	248	25	150	85	208	Self-reported, structured questionnaire
Iqbal, 2010	201	228	30	NR	192	184	24h recall
Saslow, 2017	164	152	20-50	Unclear	***41***	137	MyFitnessPal (unvalidated)
Tay, 2015 [d]	NR	NR	<50	232	74	218	7-day weighed food record
Westman, 2008	NR	NR	20	184	49 (33)	149 (46)	5-day food records
Low Carbohydrate							
Daly, 2006	NR	NR	70	Unclear	109.5	168.6	Food diary
Jonasson, 2014 [e]	167	213	90	220	***82***	182	3-day food record

Jonsson, 2009	NR	NR	Unclear	Unclear	125	196	4-day weighed food record
Sato, 2016	223	211	130	232	149 [a]	198	3-day weighed food record
Yamada, 2014	NR	NR	70-130	Unclear	***127*** (72) [a]	203 (42)	Unclear
Moderate+ Carbohydrate							
Brehm, 2009	NR	NR	174	232	***178***	209	3-day food records
deBont, 1981	139	122	<146	Unclear	***127***	137	Weighed 1-day food intake
Ellhayany, 2010	NR	NR	194	278	233	252	24h diet recall and FFQ
Esposito, 2009	305	298	225	Unclear	***209***	245	Diet diaries
Krebs, 2012 [f]	220 (68)	214 (67)	138	190	194 (57)	203 (57)	3-day dietary diary
Larsen, 2011	236	249	153	210	***166*** [a]	191 [a]	Weighed / measured food records
Milne, 1994	177	196	159	184	***166***	159	24h diet recall
Nisak, 2013	236	222	231	224	***207***	200	3-day food record
Parker, 2002 [g]	NR	NR	160	240	***166***	211	3-day weighed record
Walker 1995	172	172	160	236	***155***	188	7-day weighed food record
Watson, 2016	NR	NR	128	198	***132*** (19)	180 (22)	Semi-quantitative food records

Wolever, 2008 [h]	210	208	188	230	***199***	225	Daily key-food diaries, 3-day food records

Values are Mean (SD) where available)
NR = not reported
FFQ = food frequency questionnaire
Figures in ***bold italics*** represent intervention group adherence (within +/- 10% grams of carbohydrate) with the prescribed diet
[a] significant between-group difference
[b] **Ben-Avrahem:** assumes baseline energy intake of approx. 2,000kcal per day across all groups (not reported).
[c] **Davis:** carbohydrate was increased at 5g increments each week based on weight loss – final target carbohydrate intake unclear
[d] **Tay**: used n used in analysis (i.e. not accounting for drop outs).
[e] **Jonasson**: significant between group differences in % of energy from carbohydrate consumed at baseline – participants were informed of the diet allocation prior to baseline diet measurements were taken. Also, data reported is from 6 mo, but the study was for 24 mo.
[f] **Krebs**: significant differences in Energy and % of energy from CHO but not absolute amount of carbohydrate.
[g] **Parker:** Diets were prescriptive meal plans with many foods provided so there is no difference between the prescribed and observed intake, related to the absence of baseline data.
[h] **Wolever**: the target amount of carbohydrate is not made clear and will therefore closely resemble the actual amount consumed

Appendix Five

REC Favourable opinion & HRA Approval

Mr Paul D McArdle
St. Patrick's Centre for Community Health
Frank Street
Birmingham
B12 0YA

Email: hra.approval@nhs.net

20 September 2016

Dear Mr McArdle,

Letter of HRA Approval

Study title:	**CAADDi - Carbohydrate Awareness Advice by Dietitians in Diabetes**
IRAS project ID:	**201232**
Protocol number:	**ERN_16-0111**
REC reference:	**16/YH/0192**
Sponsor:	**University of Birmingham**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **201232**. Please quote this on all correspondence.

Yours sincerely,

Emma Stoica
Senior Assessor

Email: hra.approval@nhs.net

Copy to:

Dr Sean Jennings, Sponsor contact
Ms Priti Parmar, lead NHS R&D contact
NIHR CRN Portfolio Applications Team

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Copies of advertisement materials for research participants [CAADDi Patient Flyer - Highlighted Changes]	2.0	03 August 2016
Covering letter on headed paper [Response to HRA Queries]		24 August 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UMAL Insurance Certificate]		26 July 2016
Interview schedules or topic guides for participants [Topic Guide Patient Interviews]	1.0	14 March 2016
Interview schedules or topic guides for participants [Vignette Patient Interviews]	1.0	14 March 2016
Interview schedules or topic guides for participants [Topic Guide Dietitian Focus Groups]	1.0	14 March 2016
Interview schedules or topic guides for participants [Scenarios Dietitian Focus Groups]	1.0	14 March 2016
IRAS Application Form [IRAS_Form_25042016]		25 April 2016
Letter from sponsor [Sponsorship Letter]	1.0	20 April 2016
Letters of invitation to participant [Invite Letter Patients]	1.0	14 March 2016
Letters of invitation to participant [Invite Letter Dietitians]	1.0	14 March 2016
Notice of Substantial Amendment (non-CTIMP)	SA1	19 August 2016
Other [CAADDi Schedule of Events]	N/A	
Other [CAADDi Statement of Activities]	N/A	
Other [Confirmation of insurance letter]		20 August 2016
Other [Letter Of Intent]		01 December 2014
Other [CAADDi Case Report Form YPDM]	1.1	14 September 2016
Participant consent form [CAADDi Consent Form PWD]	1.2	14 September 2016
Participant consent form [CAADDi Consent Form YPDM]	1.1	14 September 2016
Participant consent form [Consent Dietitians]	1.0	25 April 2016
Participant information sheet (PIS) [CAADDi Participant Information Sheet PWD - Highlighted Changes]	1.3	19 September 2016
Participant information sheet (PIS) [CAADDi Participant Information Sheet RDs - Highlighted Changes]	1.3	19 September 2016
Participant information sheet (PIS) [CAADDi Participant Information Sheet YPWD - Highlighted Changes]	1.2	19 September 2016
Research protocol or project proposal [CAADDi Research Protocol]	1.2	10 June 2016
Response to Request for Further Information [Letter from Paul McArdle]		05 May 2016
Sample diary card/patient card [Case Report Form Patient]	1.0	23 March 2016
Sample diary card/patient card [Case Report Form Dietitians]	1.0	23 March 2016
Summary CV for Chief Investigator (CI) [CV Paul McArdle]	1.0	14 March 2016
Summary CV for supervisor (student research) [Cv Paramjit Gill]	1.0	14 March 2016
Summary CV for supervisor (student research) [CV Sheila Greenfield]	1.0	23 March 2016

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Priti Parmar, email: [redacted]; Tel: [redacted].

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	The HRA remit does not extend to research undertaken outside of NHS, therefore informed consent documentation and processes for the activities carried out at non-NHS entities, and respective participants, are not covered by this letter.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A Statement of Activities will act as agreement of an NHS organisation to participate. The sponsor is not requesting and does not expect any other site agreement.

Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No funding will be provided to NHS organisations in England, as specified in the Statement of Activities.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	The applicant confirmed that a standard confidentiality agreement will be in place with the transcription service before interview recordings are transferred.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	Favourable opinion was issued for the study on 9 September 2016. A substantial amendment has been subsequently submitted to the REC and favourable opinion given on 20 September 2016.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

There is one participating NHS organisation in this study, Birmingham Community Healthcare NHS Trust.

The research activities undertaken at this organisation are as follows:

1. Identification of potential participants by means of posting recruitment material (posters/flyers) on its premises, and possibly making contact with, and passing information about the study to, patients who may be interested in taking part, and/or to promote participation amongst staff.
2. Recruitment of patients for participation in Part 1): Interviews with people with type 2 diabetes.
3. Interviews with patients who prefer to come at a local NHS clinic.

Identification of participants through other means (e.g. patients through Diabetes UK voluntary groups, dietitians through existing professional networks and social media), and the focus groups with dietitians at non-NHS locations, undertaken by the sponsor through the central research team at the University of Birmingham, are outside the remit of the HRA assessment.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

The participating NHS organisation in England **will be expected to formally confirm their capacity and capability to host this research**.

- Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
- The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
Given the study activity at the participating NHS organisation, the HRA does not expect that a Principal Investigator or Local Collaborator is in place at the site. The Chief Investigator will assume responsibility for the research activities at the NHS site. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Identification of potential participants will be undertaken by staff employed by the participating NHS trust. Interviews with patients will be undertaken by the Clinical Doctoral Research Fellow who is employed by the participating trust. Therefore no additional HR arrangements are necessary.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
• The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio. • The participating NHS organisation will be asked to make available private rooms for interviews, should patients prefer to come at site premises.

Health Research Authority
Yorkshire & The Humber - Leeds West Research Ethics Committee
Room 001, Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone:

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

10 May 2016

Mr Paul D McArdle
St. Patrick's Centre for Community Health
Frank Street
Birmingham
B12 0YA

Dear Mr McArdle

Study title:	**CAADDi - Carbohydrate Awareness Advice by Dietitians in Diabetes**
REC reference:	**16/YH/0192**
Protocol number:	**ERN_16-0111**
IRAS project ID:	**201232**

The Proportionate Review Sub-committee of the Yorkshire & The Humber - Leeds West Research Ethics Committee reviewed the above application on 04 May 2016.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Miss Kirstie Penman at

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the Sub-Committee gave a **favourable** ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Widen the study to include 16-17 year old participants as possible.
2. Confirm that non-English speakers will not be excluded.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ('Participant Identification Centres'), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see 'Conditions of the favourable opinion').

Summary of discussion at the meeting

- **Social or scientific value; scientific design and conduct of the study**

  The PR Sub-Committee agreed this was a substantial amount of work for a PhD study, and queried whether the research team was confident it could be delivered. Furthermore, the PR Sub-Committee wondered how the student would be supported in achieving these aims. Following further discussion, it was agreed by the PR Sub-Committee that it would be appropriate to allow the research team to commence with the work as outlined in the proposal on the basis that the Chief Investigator would have access to robust support.

  The PR Sub-Committee appreciated the Chief Investigator's professional background and that he could signpost patients to appropriate and relevant advice but wished to obtain clarification regarding what would happen if he believed that advice was being given inappropriately by other providers and professionals.

  Mr Paul McArdle, Chief Investigator for this study, explained that if it was discovered that advice was being given inappropriately this would be noted to establish if this represented a pattern from one particular provider. The participant would also be asked if they would like this to be fed back to the provider; Mr McArdle confirmed that he could do this on their behalf.
  Mr McArdle stated that the exception to this approach would be in the case of clinically dangerous advice, which Mr McArdle confirmed that he would correct with the patient and explain to them that he would need to inform the person who provided that advice, record it as a clinical incident as part of the Trust's incident reporting system, and provide information to the participant on how to make a complaint, should they wish to do so.

  The PR Sub-Committee was satisfied with this response.

- **Recruitment arrangements and access to health information, and fair participant selection**

Members queried why the lower age limit was not lowered to include 16 and 17 year olds in line with NIHR guidance, as this was a sub-group with significant dietary issues.

Mr McArdle confirmed that the lower age limit had been updated to include sixteen and seventeen year olds. Mr McArdle went on to explain that the number of people at this age with Type 2 diabetes would be very small in comparison to the overall population of Type 2 diabetes, and the period in question for when they received the advice would likely include advice received within a paediatric service, which may differ significantly from standard advice currently provided to adults.

The PR Sub-Committee accepted the update to include 16 and 17 year old participants if possible.

The PR Sub-Committee queried whether the exclusion of non-English speakers could be justified given the prevalence of diabetes in the Asian population and the likely dietary advice needs of those who do not speak English. Furthermore, members asked whether some translation services could be provided as the study had external funding.

Mr McArdle stated that the justification for excluding non-English speakers was based on two factors. Firstly, in his clinical experience in Birmingham, Mr McArdle had discovered that there were relatively few non-English-speaking adults with Type 2 diabetes and so this would not necessarily exclude or limit this group in a significant manner. Secondly, the nature of the qualitative interview and the use of interpreters in qualitative interviewing meant that there were potential threats to validity, not least of which would occur in the analysis, such as when coding the transcripts, for example. However, Mr McArdle confirmed that he would be happy to amend the inclusion criteria and could source interpreting services should the Sub-Committee feel this justification is not sufficient.

The PR Sub-Committee confirmed its view that it was a condition of approval that this be done.

Members kindly advised that there was no need to have an arbitrary time period for participants to consider offering consent and confirmed that this could simply be given as long as the prospective participant wished to decide.

Mr McArdle thanked the Sub-Committee for this advice and confirmed that this had been amended.

The PR Sub-Committee was satisfied with the responses.

- **Suitability of supporting information**

With regards to the Participant Flyer, members suggested that the phrase ‘be involved in an exciting new diabetes study’ could be misinterpreted and could put off some people who might believe that the study was more intrusive in nature that it actually was. With this in mind, the Sub-Committee suggested that the sentence ‘would you like to help us understand more about diet and diabetes?’ would better reflect the aims of the study.

Mr McArdle thanked the PR Sub-Committee for its advice and confirmed that the flyer had been amended accordingly.

Members agreed that the Flyer needed to be checked for typographical errors.

Mr McArdle thanked the PR Sub-Committee for its advice and confirmed that the flyer had bene amended accordingly.

The PR Sub-Committee was satisfied with this response.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Patient Poster - Highlighted Changes]	1.1	05 May 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Letter]	1.0	20 April 2016
Interview schedules or topic guides for participants [Topic Guide Patient Interviews]	1.0	14 March 2016
Interview schedules or topic guides for participants [Vignette Patient Interviews]	1.0	14 March 2016
Interview schedules or topic guides for participants [Topic Guide Dietitian Focus Groups]	1.0	14 March 2016
Interview schedules or topic guides for participants [Scenarios Dietitian Focus Groups]	1.0	14 March 2016
IRAS Application Form [IRAS_Form_25042016]		25 April 2016
Letter from sponsor [Sponsorship Letter]	1.0	20 April 2016
Letters of invitation to participant [Invite Letter Patients]	1.0	14 March 2016
Letters of invitation to participant [Invite Letter Dietitians]	1.0	14 March 2016
Participant consent form [Consent Patients]	1.0	23 March 2016
Participant consent form [Consent Dietitians]	1.0	25 April 2016
Participant information sheet (PIS) [Participant Info Patients]	1.0	14 March 2016
Participant information sheet (PIS) [Participant Info Dietitians]	1.0	23 March 2016
Research protocol or project proposal [Research Protocol]	1.0	14 March 2016
Response to Request for Further Information [Letter from Paul McArdle]		05 May 2016
Sample diary card/patient card [Case Report Form Patient]	1.0	23 March 2016
Sample diary card/patient card [Case Report Form Dietitians]	1.0	23 March 2016
Summary CV for Chief Investigator (CI) [CV Paul McArdle]	1.0	14 March 2016
Summary CV for supervisor (student research) [Cv Paramjit Gill]	1.0	14 March 2016
Summary CV for supervisor (student research) [CV Sheila Greenfield]	1.0	23 March 2016

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document 'After ethical review – guidance for researchers' gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

16/YH/0192	**Please quote this number on all correspondence**

Yours sincerely
pp

Dr Sheila E. Fisher
Chair

Email:

Enclosures:	*List of names and professions of members who took part in the review*
	"After ethical review – guidance for researchers" [SL-AR2]
Copy to:	*Dr Sean Jennings, University of Birmingham* *Priti Parmar, Birmingham Community Healthcare NHS Trust*

Yorkshire & The Humber - Leeds West Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 04 May 2016

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Michael Clarke	Senior Dento Legal Advisor	Yes	
Dr Sheila E. Fisher	Retired Maxillofacial Surgeon/Clinical Research Fellow	Yes	Chair of the meeting
Mr Ashley Stratton-Powell	PhD Doctoral Training Centre for Tissue Engineering and Regenerative Medicine	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kirstie Penman	REC Assistant

Appendix Six

Participant Information & Consent

Participant Information Sheet – People with Diabetes

(FINAL Version 1.3 19/09/16)

IRAS Number 201232

Title of Study: Carbohydrate Awareness Advice

Name of Researchers: Paul McArdle
Dr Paramjit Gill (supervisor)
Professor Sheila Greenfield (supervisor)

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

What is the purpose of the study?

The aim is to understand how you have been advised about your diet and how you have used that advice. We want to learn from the experience of people with diabetes so that we can improve how we advise people about their diet in the future. It is hoped that this will then improve the quality of care for people with diabetes.

Why have I been invited?

You are being invited to take part because you have Type 2 diabetes and you have seen a dietitian in the last 1-2 years. If you know any other people with Type 2 diabetes who have also seen a dietitian, please let them know about the study also. We are planning to invite about 20 people with Type 2 diabetes to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason. This would not affect your legal rights.

What will happen to me if I take part?

If you agree to take part, a researcher will conduct an interview with you. This interview will last about 1 hour and can be arranged at a time and place to suit you. The interview will be recorded using a digital audio recorder. This recording will be transcribed (converted into text) by a professional transcription company without revealing your identity. The digital audio recorder and the audio files will be encrypted and kept on a secure, backed-up, NHS server, as outlined below.

We would also like to collect some basic information about you to help us understand the results of the study. With your permission, this can all be obtained from your medical information, or directly from you at the time of the interview, and will include:

- Gender (male / female)
- Age
- Ethnicity
- Duration of diabetes
- HbA1c (a measure of diabetes control)
- Weight and height

- Current medications

If you would like to take part, you will need to complete a consent form. If you do not read or understand spoken English, an interpreter will be required for you to take part.

Expenses and payments
Participants will not be paid to participate in the study. You should not have any out of pocket expenses.

What are the possible disadvantages and risks of taking part?
The disadvantages of taking part are very small. There is a small risk that you could reveal sensitive or personal information during the interview, but this will be handled in the strictest confidence. If you become upset or distressed during the interview, the interviewer can stop the interview.

What are the possible benefits of taking part?
We cannot promise the study will help you but the information we get from this study may help to design other research studies to determine which dietary advice is most beneficial for people with type 2 diabetes.

What happens when the research study stops?
If you are still receiving care from a dietitian or diabetes specialist, your care will continue without being changed as a result of the study.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints. Details can be obtained from your hospital. The University of Birmingham provides indemnity insurance for negligence and no fault compensation resulting from claims relating to this research study.

Will my taking part in the study be kept confidential?
We will follow ethical and legal practice and all information about you will be handled in confidence. If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the University of Birmingham who are organising the research. They may also be looked at by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All information which is collected about you during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about you which leaves the hospital will have your name and address removed (anonymised) and a unique code will be used so that you cannot be recognised from it.

The information collected, as listed above, will be used to help us to understand the results of the study into the dietary advice given by your dietitian. It will help us to see if there are differences between people with type 2 diabetes and how they use the dietary advice.

If you wish to receive a summary of the research, we will need to collect your name and address (this will be kept for 3 months after the end of the study). If you do not wish to receive a summary of the research we will not collect your name and address. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team will have access to your personal data.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

What will happen if I don't want to carry on with the study?
Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw then the information collected so far will not be erased and this information may still be used in the project analysis.

Involvement of the General Practitioner/Family doctor (GP)
Your GP does not need to be notified of your participation in this study.

What will happen to the results of the research study?
The results of the study will be used as part of a larger research study, and written up as part of the requirements to complete a research doctorate (PhD). The results of the study may also be written up for publication in a journal. You will not be identified in any report or publication. Please note that direct quotes from your interview may be used in publications, which may be identifiable.

Who is organising and funding the research?
This research is being organised by the University of Birmingham and is being funded by the National Institute of Health Research (NIHR) as part of a Clinical Doctoral Research Fellowship (reference: CDRF-2015-05-030).

Who has reviewed the study?
All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by Yorkshire & The Humber Leeds West Research Ethics Committee.

Further information and contact details

Paul McArdle
NIHR Clinical Doctoral Research Fellow
St. Patrick's Centre for Community Health
Frank Street

Dr Paramjit Gill
Reader in Primary Care Research
Primary Care Clinical Sciences
Institute of Applied Health Research

Birmingham
B12 0YA
Email: paul.mcardle@nhs.net
Phone: [redacted]

College of Medical and Dental Sciences
University of Birningham
Edgbaston
B15 2TT
Email: p.s.gill@bham.ac.uk
Phone: [redacted]

UNIVERSITY OF BIRMINGHAM

Birmingham Community Healthcare NHS
NHS Trust

CONSENT FORM – Participants
(FINAL Version 1.2 14/09/16)

Title of Study: Dietary Advice in Diabetes

REC ref: 16-YH-0192

Name of Researcher: Paul McArdle

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number ……dated..... for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw then the information collected so far will not be erased and that this information may still be used in the project analysis. ☐

3. I understand that relevant sections of my medical notes and data collected in the study may be looked at by authorised individuals from the University of Birmingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐

4. I understand that the Interview will be audio recorded and that anonymous direct quotes from the interview may be used in the study reports. ☐

5. I would like to receive a summary of the results of this study. My address for this purpose is: ☐

_____

_____

6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Appendix Seven

Patient Interview Topic Guide

Topic / Question Guide – Patient Interviews

FINAL Version 1.0 23/2/16 IRAS Number 201232

1. Tell me about the advice you've received from the dietitian…

2. Have you also had dietary advice from other health professionals?

3. Which parts of the advice have you found most helpful?

4. Which parts of the advice have you found least helpful?

5. What has most influenced any dietary changes you've made?

6. What do you understand by the term 'carbohydrate'?

7. [Introduce vignette / scenario and refer to associated questions] – see separate document.

8. What type of information do you feel would be most helpful to you in managing your diabetes, from a dietary perspective?

9. Would you like to ask any questions about what we have been talking about? I am also a Dietitian and I can answer any questions you have about your diet.

Appendix Eight

Patient Interview Scenario

Vignettes – Patient Interviews

FINAL Version 1.0 14/3/16 IRAS Number 201232

Vignette / scenario

It's about 3pm and you are feeling hungry. You ate lunch at about 1pm.

You decide to go into the kitchen and look for a snack. In the fridge you have yogurts, roast chicken slices, some leftover cheesecake, fruit salad and cheese triangles. In the cupboard there are biscuits, crisps, crackers, some unsalted nuts and dried fruit.

1. What are you thinking of having to eat?

2. What has led you to choose that?

3. What else might influence your decision on what to eat or even whether to eat?

4. How has the advice you've had from a dietitian before helped you in this situation, if at all?

Appendix Nine

Patient Case Report Form

Dietary Advice in Diabetes Study: Case Report Form – Patients

FINAL Version 1.0 23/03/16 IRAS Number 201232

Demographics etc.				
Subject initials			--- / ---	
Subject ID			--- / ---	
Age at enrolment			Years	
Gender			M/F/Other	
Ethnicity (see list below)				
Date of Interview			dd/mm/yy	
Time since most recent contact with a dietitian			Months & Years	
Number of previous contacts with RD in last 12-24 months				
Inclusion Criteria			**Yes**	**No or N/A**
A1	Adult – 18 years and over (no maximum)			
A2	Received dietary advice from a Registered Dietitian within the last 12-24 months			
A3	Ethnicity & Language – all, provided English is spoken & understood or a professional interpreter is provided			
Exclusion Criteria			**Yes**	**No or N/A**
B1	Under 18 years old			
B2	Pregnant			
B3	Uncertainty regarding type of diabetes, i.e. whether or not the patient definitely has type 2 diabetes			
B4	Presence of advanced diabetes-related or other complications requiring specific and differing nutritional advice, e.g. renal disease			
B5	Poor spoken English and the absence of interpreter			
B6	Cognitive impairment or unable to give informed consent			
Diabetes Information				
C1	Years since diagnosis			
C2	Most recent HbA1c % / mmol		Date	
C3	Weight (kg)			
C4	Height (m)			
C5	Current Diabetes Medication (including treatments for blood glucose, blood pressure / cholesterol etc.)			
C6	Notes			

1. Arab
2. Asian or Asian British – Indian
3. Asian or Asian British – Pakistani
4. Asian or Asian British – Bangladeshi
5. Asian or Asian British – any other Asian background
6. Black or Black British – Caribbean
7. Black or Black British – African
8. Black or Black British – any other Black background
9. Chinese
10. Mixed – White and Black Caribbean
11. Mixed – White and Black African
12. Mixed – White and Asian
13. Mixed – Any other mixed background
14. White – British
15. White – Irish
16. White – any other White background

Any other ethnic origin group

Appendix Ten

Focus Group Round One Topic Guide

Topic / Question Guide – Dietitian Focus Groups Round One

FINAL Version 1.0 23/2/16 IRAS Number 201232

- Initial introductions, ground rules, confidentiality etc.
- 10-15 minute presentation of the initial analysis of the patient interviews – key themes and findings.

1. What are your overall aims when advising patients with type 2 diabetes?

2. What are your views on the role of carbohydrate in type 2 diabetes?

3. How do you usually advise patients about carbohydrate in type 2 diabetes?

[Present case study / scenario number 1] – see separate document

4. How would you approach advice about carbohydrate for this patient?
    a. What factors are influencing your decisions?

[Present case study / scenario number 2] – see separate document

5. How would you approach advice about carbohydrate for this patient?
    a. What factors are influencing your decisions?

[Present case study / scenario number 3] – see separate document

6. How would you approach advice about carbohydrate for this patient?
    a. What factors are influencing your decisions?

7. What do you think are the essential skills and knowledge required by patients with respect to carbohydrate?

8. What does the term ‘Carbohydrate Awareness’ mean to you?

9. How could we clarify this term and standardise its use?

Appendix Eleven

Focus Group Scenarios

Patient Scenarios – Dietitian Focus Groups

FINAL Version 1.0 14/3/16 IRAS Number 201232

Scenario 1

Gender	Female
Age	53
Ethnicity	Asian / Asian British - Pakistani
Year of diagnosis	2008
HbA1c	69 mmol/mol
Body Mass Index	32 kgm^{-2}
Blood glucose-lowering medications	Metformin 1g twice daily Gliclazide 160mg twice daily
Lifestyle & social factors	Works full-time (sedentary), 9-5. Cooks for family.

Scenario 2

Gender	Male
Age	46
Ethnicity	White / White British
Year of diagnosis	2015
HbA1c	63 mmol/mol
Body Mass Index	38 kgm^{-2}
Blood glucose-lowering medications	None
Lifestyle & social factors	Works full-time (sedentary), night shifts. Wife cooks.

Scenario 3

Gender	Female
Age	67
Ethnicity	White / White British
Year of diagnosis	1998
HbA1c	72 mmol/mol
Body Mass Index	29 kgm^{-2}
Blood glucose-lowering medications	Metformin 1g twice daily Novomix 30, 26 units twice daily
Lifestyle & social factors	Retired. Lives alone. Busy social life including eating out, caring for grandchildren some days during the week.

Appendix Twelve

Focus Group Round Two Topic Guide

Topic / Question Guide – Dietitian Focus Groups Round Two

FINAL Version 1.0 23/2/16 IRAS Number 201232

- Initial introductions, ground rules, confidentiality etc.
- 10 minute presentation / recap of the initial analysis of the patient interviews – key themes and findings.
- 10 minutes discussion of the three papers sent for review since the previous focus group.

How can we improve carbohydrate advice to patients with Type 2 diabetes?